

**STATE OF MAINE**

**RULES FOR THE CERTIFICATION OF MARIJUANA  
CANNABIS TESTING FACILITIES**

**CODE OF MAINE RULES**

**CHAPTER 5**



**Department of Administrative and Financial Services**

**11 State House Station**

**Augusta, Maine 04333-0011**

**Effective date: September 18, 2020TBD**

**SUMMARY STATEMENT**

This rule is promulgated by the Maine Department of Administrative and Financial Services (DAFS) after consultation with the Department of Health and Human Services (DHHS), Center for Disease Control and Prevention (CDC), and the Department of Agriculture, Conservation and Forestry to establish the certification process for testing facilities analyzing marijuanacannabis and marijuanacannabis products. This rule is intended to protect public health by establishing standards for testing marijuanacannabis and providing assurance that results of testing for contaminants do not exceed the maximum level standards where testing is required.

*This is a DISCUSSION DRAFT of a routine technical rule subject to further review and comment.*

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## General

This rule is promulgated to establish the requirements for certification by the Maine Center for Disease Control and Prevention of cannabis testing facilities licensed under Maine's Adult Use Cannabis Program administered by the Office of Cannabis Policy, Department of Administrative and Financial Services, in order to mitigate potential threat to public health and safety by establishing minimum standards and procedures for the operation of cannabis testing facilities to provide information to consumers of adult use cannabis and cannabis for medical use.

The activities described in this rule may be considered a violation of federal law. Persons cultivating, manufacturing, testing, selling, purchasing or otherwise receiving adult use cannabis or cannabis for medical use, or cannabis products derived from the same, may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with this rule does not exempt licensees, their employees or customers from possible federal prosecution. Neither the Department of Administrative and Financial Services nor the Department of Health and Human Services is responsible for the actions of licensed and/or certified cannabis testing facilities under this rule.

## Section 1 – Cannabis Testing Facility Certification Program Established

### Section 1.1 – Statutory Authority

The Department of Administrative and Financial Services (referred to heretofore as DAFS), acting through its Office of Cannabis Policy (referred to heretofore as OCP), has promulgated the following rule on an emergency basis in accordance with the statutory authority provided in 28-B MRS §104, in order to mitigate potential threat to public health and safety following emergency legislative action, for the purpose of implementing, administering and enforcing the provisions of 28-B MRS, chapter 1, The Department of Health and Human Services (referred to heretofore as DHHS), acting through its Center for Disease Control and Prevention (referred to heretofore as the CDC) shall implement the certification program described herein in accordance with the statutory authority provided in 22 MRS § 569.

### Section 1.2 - Department Authority

DAFS and DHHS, through the CDC, may enforce this Rule and any relevant provisions of Titles 4, 5, 22 and 28-B, and any other general statutes, laws, executive orders or subsequently passed legislation. DAFS shall set licensing fees in accordance with 28-B MRS § 207, and CDC shall set certification and technology fees in accordance with 22 MRS § 569. DAFS, DHHS or an agent thereof shall have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, any cannabis testing facility and its business records. DAFS shall further have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, vehicles used to transport cannabis or cannabis products to a cannabis testing facility. Approval by the CDC of the plans, standard operating procedures, financial and business arrangements or other documents and information provided for certification by the CDC during the certification process does not constitute approval by DAFS for the purposes of licensure pursuant to the *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1.

### Section 1.3 - Communication with DAFS and/or DHHS

**1.3.1 Written Communications.** If an applicant or licensee is required to or elects to submit anything in writing to DAFS or DHHS, unless otherwise prescribed by DAFS or DHHS, the applicant or licensee may submit the writing to DAFS or DHHS via:

- A. Mail;
- B. In-person delivery;

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- C. Facsimile; or
- D. E-mail.

**1.3.2 Submission Deadline.** If a written notification must be submitted by a deadline it must be received by DAFS or DHHS, regardless of method used to submit the writing, by 5 p.m. Eastern Time.

## Section 1.4 – Definitions

1. **A<sub>w</sub>** means the water activity, which is the partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water. It is a measure of the quantity of water in a product that is available, and therefore capable of, supporting bacteria, yeasts and fungi.
2. **Acceptance criteria** means the specified limits placed on characteristics of an item, process or service that are used to determine data quality as defined in methods, rules or regulations.
3. **Accredited** means to be recognized as conforming to a standard by an accrediting organization, such as ISO/IEC 17025.
4. **Accredited college or university** is a college or university accredited by a regional or national accrediting agency recognized by the United States Department of Education.
5. **Accuracy** means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are a result of sampling and analytical operations; a data quality indicator.
6. **Action level** is the threshold value for determining whether a sample passes or fails an analytical test.
7. **Adult use cannabis** means cannabis cultivated, manufactured, distributed or sold by a cannabis establishment.
8. **Adult use cannabis product** means a cannabis product that is manufactured, distributed or sold by a cannabis establishment.
9. **Aliquot** is a portion of a sample that is used in an analysis performed by a testing facility.
10. **Analyst** means the designated individual who tests the samples by performing the “hands-on” analytical methods and associated techniques. The analyst is responsible for applying required testing facility practices and other pertinent quality controls to meet the required level of quality.
11. **Analyte** is a chemical, compound, element, bacteria, yeast, fungus or toxin that is identified or measured.
12. **Analytical batch** means a group of samples that is prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.
13. **Analytical method** is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.
14. **AOAC International** means Association of Official Agricultural Chemists International, a non-profit scientific association that creates, validates and publishes reliable analytical test methods.

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15. **Apparent activity** means any sight, sound, smell or other indication that persons are present at a cannabis establishment.
16. **Applicant** means a person who submits to certification by the Maine CDC as part of an application for a license to operate a cannabis testing facility issued by OCP.
17. **Approved proficiency testing provider** means a provider of proficiency testing samples whom the certification officer has deemed to meet the requirements of this Rule.
18. **Assessment** means the evaluation process used to measure or establish the performance effectiveness and conformance of a testing facility and/or its systems to defined criteria and standards and requirements of testing facility certification.
19. **Audit** means a systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and reporting aspects of a system to determine whether quality assurance, quality control and technical activities are being conducted as planned. An audit is conducted to determine whether these activities will effectively achieve quality objectives.
20. **Batch** means:
- A harvest batch; or
  - A production batch.
21. **Batch number** means a distinct group of numbers, letters or symbols, or any combination thereof, assigned to a specific batch of adult use cannabis by a cultivation facility, sample collector, testing facility, or a cannabis store or to a specific batch of adult use cannabis or adult use cannabis products by a products manufacturing facility, sample collector, testing facility or a cannabis store.
22. **Best Practices Guide** means the *Best Practices for the Sampling of Adult Use Cannabis*, published by the Department, incorporated by reference in 18-691 CMR, ch.1. All licensees and any employee of a licensee collecting samples of cannabis, cannabis concentrate, or cannabis products for mandatory testing must collect samples in accordance with the best practices described in the guide.
23. **Bias** means the systematic or persistent distortion of a measurement process, which causes errors in one direction, resulting in the expected sample measurement being different from the sample's true value.
24. **Calibration** means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by standards.
- In calibration of support equipment, the values realized by standards are established using reference standards that are traceable to the International System of Units (SI).
  - In calibration, per methods, the values realized by standards are typically established using reference materials that are either purchased by the testing facility with a certificate of analysis or purity or prepared by the testing facility using support equipment that has been calibrated or verified to meet specifications.
25. **Calibration curve** means the mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
26. **Calibration standard** means a substance or reference material used for calibration.

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27. **Cannabinoid** is a chemical compound that is unique to, and derived from, **cannabis**.
28. **Cannabis** means the leaves, stems, flowers and seeds of a cannabis plant, whether growing or not. “Cannabis” includes cannabis concentrate, except where context indicates otherwise, but does not include hemp as defined in 7 MRS §2231, or a cannabis product.
29. **Cannabis concentrate** means the resin extracted from any part of a cannabis plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin, including, but not limited to hashish. In determining the weight of a cannabis concentrate in a cannabis product, the weight of any other ingredient combined with cannabis or cannabis concentrate to prepare the cannabis product may not be included.
30. **Cannabis flower** means the pistillate reproductive organs of a mature cannabis plant, whether processed or unprocessed, including the flowers and buds of the plant. Cannabis flower does not include cannabis trim or whole mature cannabis plants.
31. **Cannabis plant** means all species of the plant genus cannabis. Including but not limited to a mother plant, a mature cannabis plant, an immature cannabis plant or a seedling, but it does not include a cannabis product or “hemp” as defined in 7 MRS § 2231.
32. **Cannabis product** means a product composed of cannabis or cannabis concentrate and other ingredients that is intended for use or consumption. “Cannabis product” includes without limitation an edible cannabis product, a cannabis ointment and a cannabis tincture. Cannabis product does not include cannabis concentrate.
33. **Cannabis store** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 to purchase adult use cannabis, immature cannabis plants and seedlings from a cultivation facility, to purchase adult use cannabis and adult use cannabis products from a products manufacturing facility, to collect and transport samples of cannabis, cannabis concentrate and cannabis products in that cannabis store’s possession for mandatory testing, and to sell adult use cannabis, adult use cannabis products, immature cannabis plants and seedlings to consumers.
34. **Cannabis testing facility** means an entity licensed according to 28-B MRS §503, including those also registered as cannabis testing facilities in accordance with 22 MRS §2423-A, to test cannabis, cannabis products and other substances for research and development and to analyze contaminants in and the potency and cannabinoid profile of samples in an approved location.
35. **Cannabis trim** means any part of a cannabis plant, whether processed or unprocessed, that is not cannabis flower or a cannabis seed.
36. **Cannabis waste** means cannabis, cannabis plants or cannabis products that are unfit for retail sale for reasons including without limitation failed mandatory testing, expired products or crop failure.

~~— In calibration of support equipment, the values realized by standards are established using reference standards that are traceable to the International System of Units (SI).~~

- ~~a. — In calibration, per methods, the values realized by standards are typically established using reference materials that are either purchased by the testing facility with a certificate of analysis or purity or prepared by the testing facility using support equipment that has been calibrated or verified to meet specifications.~~

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~~— **Calibration curve** means the mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.~~

~~23. **Calibration standard** means a substance or reference material used for calibration.~~

24.37. **CAS number** is the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service (CAS).

25.38. **CBD** is cannabidiol, CAS number 13956-29-1.

26.39. **CBDA** is cannabidiolic acid, CAS number 1244-58-2.

27.40. **Certificate of analysis** means the report prepared for the requester and **OCP** about the analytical testing performed and results obtained by the testing facility.

28.41. **Certification** means the process by which an agency or organization evaluates and recognizes a testing facility as meeting certain predetermined qualifications or standards, thereby certifying the testing facility. The Department of Health and Human Services is responsible for certification of all testing facilities.

29.42. **Certification officer** means the person designated by the Department of Health and Human Services to manage certification of testing facilities.

30.43. **Certified reference material** means reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute.

31.44. **Chain of custody form** means a record, either paper-based or electronic, that documents the possession of the samples at the time of receipt by the **cannabis** testing facility, in accordance with chain of custody protocol prescribed by the **cannabis** testing facility. This record, at a minimum, must include the sample location, the number and types of containers, the mode of collection, the authorized individual who collected the sample, the date and time of collection, preservation and requested analyses.

32.45. **Chain of custody protocols** means the procedures developed and employed by the **cannabis** testing facility to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a chain of custody form that documents the collection, transport and receipt of compliance samples by the **cannabis** testing facility. In addition, these protocols document all handling of the samples within the **cannabis** testing facility and, if applicable, by the sample collector or self-sampler.

33.46. **Colony forming unit (CFU)** means a unit of measurement of estimated number of bacteria or fungal cells in a sample.

34.47. **Contaminant** means an unacceptable level of an unwanted or objectionable substance, toxin, pollution or foreign material that causes impurity in a product. Contaminants include, but are not limited to, pesticides, microbiology, filth, heavy metals and residual chemical solvents.

35.48. **Corrective action** means an action taken by the **cannabis** testing facility to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance.

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- 36.49. **Corrective action plan** means a report, including specific corrective actions and a specific date of completion, generated in response to deficiencies or findings of non-compliance.
- 37.50. **Cultivar** means a specific variety of cannabis produced by selective breeding. Also commonly referred to as a “strain” of cannabis.
- 38.51. **Cultivation facility** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 to purchase cannabis plants and seeds from other cultivation facilities; to cultivate, prepare and package adult use cannabis; to collect and transport samples of cannabis cultivated by that facility for mandatory testing; to sell adult use cannabis to products manufacturing facilities, to cannabis stores and to other cultivation facilities; and to sell cannabis plants and seeds to other cultivation facilities and immature cannabis plants and seedlings to cannabis stores. A cultivation facility includes a nursery cultivation facility. Licensees that cultivate cannabis in a nursery cultivation facility may sell an unlimited number of cannabis seeds and a sum total of 12 seedlings and immature plants to a consumer 21 years of age or older.
- 39.52. **Cultivator** means a cultivation facility licensed under 28-B MRS, Chapter 1, subchapters 2 and 3 or a person, qualifying patient, exempt caregiver, registered caregiver or registered dispensary that is authorized under 22 MRS, chapter 558-C to cultivate cannabis.
- 40.53. **Deficiency** means a failure of the testing facility to meet any one of the requirements in this rule.
- 41.54. **Demonstration of capability** means a procedure to establish the ability of the analyst to generate acceptably accurate and precise analytical results.
- 42.55. **Department of Administrative and Financial Services (DAFS)** means the Maine Department of Administrative and Financial Services. DAFS includes the Office of Cannabis Policy (OCP), which licenses adult use cannabis establishments, including cannabis testing facilities, and registers medical cannabis program participants including patients, registered caregivers, registered dispensaries, registered manufacturing facilities and registered inherently hazardous extraction facilities.
- 43.56. **Department of Health and Human Services (DHHS)** means the Maine Department of Health and Human Services. DHHS includes the Maine Center for Disease Control and Prevention (CDC), which certifies, through its Maine Cannabis Certification Program, the technology and testing methods used by cannabis testing facilities under this Rule.
- 44.57. **Disciplinary action** means any action taken by the CDC to limit, suspend, revoke, or deny the certification of a cannabis testing facility as a result of the cannabis testing facility’s violation or other nonconformance with this rule, 28-B MRS, chapter 1, or other rules promulgated by DHHS or DAFS.
- 45.58. **Edible cannabis product** means a cannabis product intended to be consumed orally, including, but not limited to, any type of food, drink or pill containing cannabis.
- 46.59. **Exempt caregiver** means a medical cannabis caregiver who is exempt from the registration requirements of 22 MRS § 2425-A.
- 47.60. **Facility director** means the individual who is legally authorized to direct the activities of a testing facility and who commits the appropriate resources to comply with this rule.
- 48.61. **Field of testing** means those programs, matrices, methods or analyte combinations, for which certification is offered.

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62. **Final form** means for the purpose of mandatory testing, adult use cannabis or an adult use cannabis product that is in the form that will be sold to an adult use cannabis consumer; except that the adult use cannabis or adult use cannabis product need not be prepackaged into individual retail units to be considered in its “final form”.
- 49.63. **Finished plant material** means ~~cannabis~~ that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds and any dead leaves or stems.
- 49.63. **Finished plant material** means ~~marijuana~~~~cannabis~~ that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds and any dead leaves or stems.
- 50.64. **Foreign material** means any physical contaminant or filth, including without limitation hair, insects, feces, packaging contaminants and manufacturing waste and by-products.
- 51.65. **Full active license** means a license issued by the Department of Administrative and Financial Services, Office of ~~Cannabis~~ Policy to a ~~cannabis~~ testing facility that has received CDC full certification and ISO/IEC 17025:2017 or most recent version accreditation for at least one technology and analyte that authorizes testing of ~~cannabis~~ or ~~cannabis~~ products in accordance with 28-B MRS, Chapter 1, subchapters 2 and 6 and this rule.
- 52.66. **Full certification** means certification granted by the CDC to a ~~cannabis~~ testing facility that has received ISO/IEC 17025:2017 or most recent version accreditation and meets all other requirements of this Rule and authorizing it to seek an active license from DAFS.
- 53.67. **Harvest batch** means a specific quantity of adult use ~~cannabis~~ harvested from adult use ~~cannabis~~ plants of the same cultivar, grown under the same conditions, and harvested during a specified period of time from a specified cultivation area within a cultivation facility.
- 54.68. **Homogeneity** means the amount of ~~cannabis~~ or ~~cannabis~~ concentrate and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or each portion of the product or concentrate, or a representative sample.
- 55.69. **Increment or sample increment** means a smaller sample that, together with other increments, makes up the primary sample.
- 56.70. **ISO/IEC 17025:2017** or most recent version means the general requirements for the competence of testing and calibration laboratories issued in 2017 (or more recent) joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission.
- 57.71. **Licensee** means a natural person or business entity licensed pursuant to 28-B MRS, Chapter 1, subchapters 2 and 5 to operate an adult use ~~cannabis~~ establishment.
- 58.72. **Limit of detection (LOD)** means an estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect.
- 59.73. **Limit of quantitation** means the minimum level, concentration or quantity of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.
- 60.74. **Manufacturer** means a manufacturing facility licensed under 28-B MRS, Chapter 1, subchapter 2 or a person, qualifying patient, registered caregiver or registered dispensary that is legally allowed to manufacture under 22 MRS, chapter 558-C.
60. ~~MarijuanaCannabis concentrate means the resin extracted from any part of a marijuanacannabis plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin, including, but~~  
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- ~~not include immature marijuanacannabis plants and seedlings, but it does include marijuanacannabis plants and seedlings that are intended for sale or consumption.~~
61. **MarijuanaCannabis flower** means the pistillate reproductive organs of a mature marijuanacannabis plant, whether processed or unprocessed, including the flowers and buds of the plant. MarijuanaCannabis flower does not include marijuanacannabis trim or whole mature marijuanacannabis plants.
- **MarijuanaCannabis plant** means all species of the plant genus *cannabis*. Including but not limited to a mother plant, a mature marijuanacannabis plant, an immature marijuanacannabis plant or a seedling, but it does not include a marijuanacannabis product or “hemp” as defined in 7 MRS § 2231.
62. **MarijuanaCannabis product** means a product composed of marijuanacannabis or marijuanacannabis concentrate and other ingredients that is intended for use or consumption. “MarijuanaCannabis product” includes without limitation an edible marijuanacannabis product, a marijuanacannabis ointment and a marijuanacannabis tincture. MarijuanaCannabis product does not include marijuanacannabis concentrate.
62. **MarijuanaCannabis store** means a facility licensed under Title 28-B and 18-691-CMR, ch. 1 to purchase adult use marijuanacannabis, immature marijuanacannabis plants and seedlings from a cultivation facility, to purchase adult use marijuanacannabis and adult use marijuanacannabis products from a products manufacturing facility, to collect and transport samples of marijuanacannabis, marijuanacannabis concentrate and marijuanacannabis products in that marijuanacannabis store’s possession for mandatory testing, and to sell adult use marijuanacannabis, adult use marijuanacannabis products, immature marijuanacannabis plants and seedlings to consumers.
62. **MarijuanaCannabis testing facility** means an entity licensed according to 28-B MRS §503, including those also registered as marijuanacannabis testing facilities in accordance with 22 MRS §2423-A, to test marijuanacannabis, marijuanacannabis products and other substances for research and development and to analyze contaminants in and the potency and cannabinoid profile of samples in an approved location.
62. **MarijuanaCannabis trim** means any part of a marijuanacannabis plant, whether processed or unprocessed, that is not marijuanacannabis flower or a marijuanacannabis seed.
62. **MarijuanaCannabis waste** means marijuanacannabis, marijuanacannabis plants or marijuanacannabis products that are unfit for retail sale for reasons including without limitation failed mandatory testing, expired products or crop failure.
- 63.75. **Matrix** means the component or substrate that contains the analyte of interest.
- 64.76. **Matrix spike** means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound. The spiked concentration must be at a low to mid-range concentration of the calibration curve for the target analyte.
- 65.77. **Method** means a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis or quantification), systematically presented in the order in which they are to be executed.
- 66.78. **Method blank** means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation and is processed in exactly the same manner as the samples.
- 67.79. **Method detection limit** means the minimum measured concentration of a substance that can be reported with 99-percent confidence that the measured analyte is distinguishable from method blank results.
- 70.80. **Mycotoxin** means any toxic substance produced by a fungus and especially a mold.

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- 71.81. **National Institute of Standards and Technology (NIST)** means a federal agency of the United States Department of Commerce's Technology Administration.
- 72.82. **Nonconformance or noncompliance** means a failure of a testing facility to meet any requirement in this rule.
- 73.83. **Non-target organism** means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.
- 74.84. **Percent recovery** means the percentage of a measured concentration relative to the added (i.e. spiked) concentration in a reference material, matrix spike sample or matrix spike duplicate. A testing facility shall calculate the percent recovery by dividing the sample result by the expected result then multiplying the quotient by 100.
- 75.85. **Pesticide** means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; and any nitrogen stabilizer; and all substances listed in Table 6.8-A of this Rule. It does not include multicellular biological controls such as mites, nematodes, parasitic wasps, snails or other biological agents not regulated as pesticides by the U.S. Environmental Protection Agency.
- 76.86. **Plant growth regulator** means any substance or mixture of substances intended through physiological action for accelerating or retarding the rate of growth or rate of maturation or for otherwise altering the behavior of plants or the produce thereof. "Plant growth regulator" does not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants or soil amendments.
- 77.87. **Practical experience** means hands-on post-secondary-education testing facility experience, using equipment, instruments, kits and materials routinely found in a testing facility.
- 78.88. **Precision** means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision serves as a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
- 79.89. **Preservation** means any conditions under which a sample must be kept to maintain chemical and/or biological integrity prior to analysis.
- 80.90. **Primary sample** means a portion of cannabis or cannabis products collected from a harvest or production batch for testing. Also called a "composite" sample.
- 81.91. **Production batch** means a specific quantity of cannabis concentrate or a cannabis product that is produced during a specified period of time using the same extraction and/or manufacturing method, formulation and/or recipe and standard operating procedure. "Production batch" also includes the combination of two or more harvest batches of cannabis trim or kief.
- 82.92. **Products manufacturing facility** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 to purchase adult use cannabis from a cultivation facility or another products manufacturing facility; to manufacture, label and package adult use cannabis and adult use cannabis products; to collect and transport samples of cannabis, cannabis concentrate and cannabis products manufactured by that facility for mandatory testing; and to sell adult use cannabis and adult use cannabis products to cannabis stores and to other products manufacturing facilities

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83.93. **Proficiency test** means an evaluation of a testing facility's performance against pre-established criteria, by means of inter-testing facility comparisons of test measurements.

84.94. **Proficiency test sample** means a sample prepared by a party independent of the testing facility tasked with evaluating the sample, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing facility evaluating the sample and its personnel.

85.95. **Provisional certification** means the process by which CDC evaluates and recognizes a cannabis testing facility as meeting the requirements of this Rule with the exception ISO/IEC 17025 accreditation, for which an application must be pending.

86.96. **Provisional active license** means a license issued by DAFS to a cannabis testing facility that has received CDC provisional certification and has applied for, but not yet received, ISO/IEC 17025:2017 or most recent version accreditation for at least one technology and analyte that authorizes testing of cannabis or cannabis products in accordance with 28-B MRS, Chapter 1, subchapter 2 and 6 and this rule.

97. **Proficiency test sample** means a sample, the composition of which is unknown to the testing facility, provided to test whether the testing facility can produce analytical results within the specified acceptance criteria.

87.98. **Proficiency testing** means a way to evaluate a testing facility's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.

88.99. **Proficiency testing program** means the aggregate of providing rigorously controlled and standardized samples to a testing facility for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating testing facilities.

89.100. **Protocol** means the detailed written procedure for field and/or testing facility operation (e.g., sampling, analysis) that must be strictly followed.

90.101. **Qualifying patient** means a person who possesses a valid certification for the medical use of cannabis pursuant to 22 MRS § 2423-B.

91.102. **Quality assurance (QA)** means a set of operating principles that enable testing facilities to produce defensible data of known accuracy and precision. Quality assurance includes without limitation employee training, equipment preventative maintenance procedures, calibration procedures and quality control testing.

103. **Quality assurance manual** means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability and implementation of an agency, organization or cannabis testing facility, to ensure the quality of its product and the utility of its product to its users.

92.104. **Quality control (QC)** means the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet the stated requirements established by the client; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

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93.105. **Quality control sample** means a sample used to assess the performance of all, or a portion of, the measurement system. One of any number of samples, such as certified reference materials, a matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

93. ~~Quality assurance manual means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability and implementation of an agency, organization or marijuana testing facility, to ensure the quality of its product and the utility of its product to its users.~~

94.106. **Quality system** means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability and implementation plan of an organization for ensuring quality in its work processes, products (items) and services. The quality system provides the framework for planning, implementing and assessing work performed by the organization and for carrying out required QA and QC activities. A cannabis testing facility's quality system must account for anomalies arising from the collection and transport of samples for mandatory testing conducted by a self-sampler or a sample collector licensee, including provisions regarding the use of blanks.

95.107. **Quantitate** means to undertake the arithmetic process of determining the amount of analyte in a sample.

96.108. **Raw data** means the documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, un-tabulated sample results, QC sample results, chromatograms, instrument outputs and handwritten records.

97.109. **Reagent** means a compound or mixture added to a system to cause a chemical reaction, or test if a reaction occurs. A reagent may be used to determine whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

98.110. **Reference material** means a material or substance, one or more of which the property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

99.111. **Reference method** means a method by which the performance of an alternate method is measured or evaluated.

100.112. **Registered caregiver** means a caregiver who is registered by OCP pursuant to 22 MRS § 2425.

101.113. **Registered dispensary** or **dispensary** means an entity registered under 22 MRS § 2425-A that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, sells, supplies or dispenses cannabis or related supplies and educational materials to qualifying patients and the caregivers of those patients.

102.114. **Relative standard deviation** means the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100 and is calculated using the following equation:  $RSD = (s / \bar{x}) \times 100\%$ , where  $s$  = standard deviation and  $\bar{x}$  = mean recovery. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used.

103.115. **Reporting limit** means the lowest level of an analyte that can be accurately recovered from the matrix of interest (e.g., the level of quantitation).

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104.116. **Requester** means a person who submits a request to a certified testing facility for state-mandated testing of cannabis or cannabis products.

105.117. **Sample** means, as applicable, an amount of:

- a. Cannabis, cannabis concentrate or cannabis product collected from an adult use cannabis establishment for mandatory testing:
  - i. By an employee of a testing facility in accordance with 28-B MRS § 604 and *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1;
  - ii. By a sample collector, in accordance with 28-B MRS § 604 and 18-691 CMR, ch. 1; or
  - iii. By a self-sampler in accordance with 28-B MRS § 604-A and 18-691 CMR, ch.1;
- b. Cannabis, cannabis concentrate or cannabis product provided to a testing facility by a cannabis establishment or other person for mandatory testing or testing for research and development purposes in accordance with 28-B MRS, chapter 1;
- c. Adult use cannabis or adult use cannabis product collected from a licensee by the Department for the purposes of testing the cannabis or cannabis product for quality control purposes pursuant to 28-B MRS §512(2).

106.118. **Sample collection SOP** means a standard operating procedure for the collection of samples of cannabis, cannabis concentrate and cannabis products for mandatory testing published by the Department that must be used by all licensees collecting, transporting and transferring samples for mandatory testing. The current sample collection SOP is Appendix A of *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1.

107.119. **Sample collector** means a person licensed pursuant to 18-691 CMR, ch. 1 and 28-B MRS, ch. 1 to collect samples of cannabis and cannabis products for testing and to transport and deliver those samples to a testing facility. A sample collector must hold a valid individual identification card ("IIC").

108.120. **Sample increment** means a portion of a batch that, together with other increments, makes up the sample.

109.121. **Sampling date** means the date that a sample was collected in the field, in order to be reported as such, when reporting the sample results to testing facility clients or regulatory programs.

110.122. **Sanitize** means to sterilize, disinfect or make hygienic.

111.123. **Self-sampler** or **Self-sampling licensee** means a cultivation facility, products manufacturing facility or cannabis store licensee that collects samples of cannabis, cannabis concentrate and cannabis products for mandatory testing or an employee of a cultivation facility, products manufacturing facility or cannabis store licensee who collects samples of cannabis, cannabis concentrate and cannabis products for that licensee for mandatory testing. Any individual collecting samples for mandatory testing must hold a valid individual identification card ("IIC").

112.124. **Solid** means a matrix that includes soils; sediments; solid waste; and sludges.

113.125. **Standard** means the certified reference materials produced by NIST or other equivalent organization and characterized for absolute content, independent of analytical method or the dilutions made

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from these certified reference materials for the purposes of calibration or determining accuracy of a test method.

~~114.~~126. **Standard operating procedure (SOP)** means a written document that details the method for an operation, analysis or action, with thoroughly prescribed techniques and steps. SOPs are officially approved by the testing facility's senior management as the methods for performing certain routine or repetitive tasks.

~~127.~~127. **Target or target analyte** means an analyte or list of analytes within a test method that may be analyzed and for which the testing facility has obtained certification from the certification officer to test as part of a field of testing.

~~127.~~127. **Target or target analyte** means an analyte or list of analytes within a test method that may be analyzed and for which the testing facility has obtained certification from the certification officer to test as part of a field of testing.

~~117.~~128. **Target organism** is an organism that is being tested for in an analytical procedure or test method.

~~117.~~128. **Target organism** is an organism that is being tested for in an analytical procedure or test method.

~~118.~~129. **Technology** means a specific arrangement of analytical instruments, detection systems and/or preparation techniques.

~~119.~~130. **Technology Analyte Table (TAT)** means the table used to identify methods, analytes, programs and matrices available for certification.

~~120.~~131. **Testing or test** means the research and analysis of cannabis, cannabis products or other substances for contaminants, safety or potency. "Testing" or "test" includes the collection of samples of cannabis and cannabis products for testing purposes but does not include cultivation or manufacturing. Nothing in this definition shall be construed to permit any licensee except a cannabis testing facility to perform analyses of cannabis, cannabis concentrate or cannabis products for mandatory testing without a separate cannabis testing facility license issued by DAFS.

~~121.~~132. **THC** is tetrahydrocannabinol (delta-9 THC), CAS number 1972-08-3.

~~122.~~133. **THCA** is tetrahydrocannabinolic acid, CAS number 23978-85-0.

~~134.~~134. **Tincture** means a liquid edible cannabis product with a concentration of greater than 1 mg of THC per ounce of liquid.

~~123.~~135. **Total CBD** means the sum of CBD and CBDA. Total CBD is calculated using the following equation: Total CBD = CBD + (CBDA\*0.877).

~~124.~~136. **Total THC** means the sum of THC and THCA. Total THC is calculated using the following equation: Total THC = delta-9 THC + (THCA\*0.877).

~~126.~~137. **Total Yeast and Mold Count (TYMC)** means the total combined yeast and mold count in standardized plating methodologies and is usually expressed in number of colony forming units (CFU).

~~127.~~138. **Traceability** means the ability to trace the history, application or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties or reference materials. In

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a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

**128.139. Unusable** means that the cannabis can no longer be smoked, eaten, ingested, topically applied or otherwise ingested. Nor can the cannabis be further manipulated in a manner to extract more than a trace amount of cannabinoid.

**129.140. Validation** means the confirmation by examination and objective evidence that the requirements for a specific intended use are fulfilled.

**130.141. Verification** means the confirmation by examination of, and provision of, objective evidence that specified requirements have been fulfilled. Verification refers to the process of examining a result of a given activity to determine conformance with this rule.

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## Section 2 – General CDC Certification and ISO/IEC 17025: 2017 Accreditation Requirements Prior to Issuance of a Cannabis Testing Facility License

### Section 2.1 – Certification of Cannabis Testing Facility Required Prior to Issuance of a Full Active or Provisional Active License

A cannabis testing facility must obtain certification by DHHS, CDC, as described in this Rule, before DAFS, OCP will issue to that cannabis testing facility a full active or provisional active license.

#### 2.1.1. Cannabis Testing Facility General Requirements. The cannabis testing facility must:

- A. Be an entity that can be held legally responsible;
- B. Carry out its testing activities in such a way as to meet the requirements of this rule and to meet the needs of clients in accordance with the cannabis testing facility's quality assurance manual;
- C. Employ technical management and personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties and identify departures from the management system and initiate actions to prevent or minimize such departures;
- D. Use personnel employed by, or under contract to, the cannabis testing facility, and where contracted and additional technical and key support personnel are used, ensure that such personnel are supervised and competent and that they work in accordance with the cannabis testing facility's quality system;
- E. Have a written policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work or diminish confidence in its competence, impartiality, judgement or operational integrity. Submission of this policy for the purposes of certification does not fulfill licensing requirements regarding undue influence evaluated by OCP, such information will be evaluated by OCP independent of any assessment made by the CDC;
- F. Have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
- G. Authorize specific personnel to perform particular types of sampling, if applicable, and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
- H. Authorize specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.

**2.1.2. Certification may be full or provisional.** A cannabis testing facility must receive from the CDC full or provisional certification for at least one analyte and technology to be used for the testing of adult use cannabis and adult use cannabis products before that cannabis testing facility can seek a full active or provisional active license from OCP.

- A. Full certification will be granted by the CDC to a cannabis testing facility that can demonstrate that it has applied for and received ISO/IEC 17025:2017 or most recent version accreditation and that it meets all other requirements of this Rule.
- B. Provisional certification will be granted by the CDC to a cannabis testing facility that can demonstrate that it has had an application accepted for, but has not yet received nor been denied, ISO/IEC 17025:2017 or most recent version accreditation and that meets all other requirements of this rule.
- C. Certification may be denied when an applicant has deficiencies and the certification officer determines that the applicant cannot consistently produce valid data.

### Section 2.2 - ISO/IEC 17025:2017 or most recent version Accreditation Requirements for CDC Cannabis Testing Facility Certification

**2.2.1. The ~~marijuana~~cannabis testing facility must demonstrate ISO/IEC 17025: 2017 accreditation before the CDC will issue a full testing facility certification.** The ~~marijuana~~cannabis testing facility may apply for full

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certification for only those fields of testing accredited by ISO/IEC 17025:2017 or most recent version. The ~~marijuana~~cannabis testing facility may apply for an ~~OMP~~OCP-issued full active license for only those fields of testing for which it has received ISO/IEC 17025:2017 or most recent version accreditation and CDC certification. An on-site inspection by CDC will be required.

**2.2.2. The cannabis testing facility must apply for ISO/IEC 17025:2017 or most recent version accreditation before the CDC will issue a provisional testing facility certification.** A cannabis testing facility applicant meeting all general requirements for certification, except for ISO/IEC 17025:2017 or most recent version accreditation, may apply to the CDC for provisional certification by submitting a complete application and required fees. Following an on-site inspection of an applicant that has not received ISO/IEC 17025:2017 or most recent version accreditation, the CDC will perform a review of data validation studies and a review of all other proof that the cannabis testing facility has met certification requirements, and if the CDC determines the cannabis testing facility meets all requirements, the CDC may grant the applicant a provisional certification. The provisional certification, if granted, expires 12 months from the date of issuance.

- A. The cannabis testing facility may apply for an OCP-issued provisional active license for only those fields of testing included in the application for ISO/IEC 17025:2017 or most recent version accreditation.
- B. Upon receipt of ISO/IEC 17025:2017 or most recent version accreditation, the cannabis testing facility must demonstrate proof of accreditation to OCP and the CDC within 5 business days. Upon receipt of such notice and following confirmation of accreditation, the CDC will issue to the cannabis testing facility full certification for the accredited technologies and analytes which will expire on the same date as the originally issued provisional certification. A cannabis testing facility can request a change in licensure status from provisional active to full active licensure for the remainder of the term of the originally issued provisional active license. Nothing in this section shall be construed to extend the term of certification or licensure beyond the term of the originally issued provisional certification or provisional active licensure.
- C. Before the expiration of its provisional certification, the cannabis testing facility must obtain ISO/IEC 17025:2017 or most recent version accreditation for at least one field of testing included in its accreditation application; otherwise it must cease all operations until such accreditation is obtained for at least one field of testing.
- D. If ISO/IEC 17025:2017 or most recent version accreditation is denied to the cannabis testing facility holding provisional certification, the facility must notify the CDC of the denial within one business day of receipt of the denial. The CDC shall revoke the provisional certification, upon the cannabis testing facility's notification of denial of ISO/IEC 17025:2017 or most recent version accreditation. Upon revocation of a provisional certification by the CDC, OCP shall revoke immediately the cannabis testing facility's provisional active license.

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## Section 3 – Certification of Testing Facilities

### Section 3.1 - Certification Required

A cannabis testing facility may test cannabis or cannabis products only if it holds a current certification from DHHS, CDC. Initial certification will be for a period of 1 year, and annual recertification is required.

#### 3.1.1. Applications must meet all CDC requirements.

- A. At a minimum, the application for certification must include:
  - (1) The name of the facility director in charge of the cannabis testing facility and each employee's qualifications or job descriptions;
  - (2) Resumes that document appropriate experience and education, including college transcripts and evidence of a completed degree, for personnel specified in section 4;
  - (3) A quality assurance manual, meeting the specifications of subsection 3.2;
  - (4) Standard operating procedures, meeting the specifications of subsection 3.3; and
  - (5) The fields of testing for which the applicant seeks provisional certification or certification using the technology analyte table (TAT) maintained by the program and proof of ISO/IEC 17025:2017 or most recent version accreditation for such fields of testing or, if applying for a provisional certification, proof that the applicant has submitted an approved application for ISO/IEC 17025:2017 or most recent version accreditation for such fields of testing.
- B. Applications for certification will not be considered complete until payment of the non-refundable application fee.
- B.C. Applications for renewal certification shall be submitted no less than sixty days prior to the expiration of current certification.
- C.D. The cannabis testing facility must submit the following additional documentation to obtain provisional or full certification from the CDC:
  - (1) A description of the organization and management structure of the cannabis testing facility, its place in any parent organization and the relationships between quality management, technical operations and support services;
  - (2) A management plan defining the responsibilities of key personnel in the organization who have any involvement or influence on the testing, and if the cannabis testing facility is part of an organization performing activities other than testing, identifying potential conflicts of interest;
  - (3) Written policies and procedures that ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
  - (4) Written policies and procedures for receipt of samples for mandatory or other testing; and
  - (5) A written policy defining legal chain of custody protocols and including procedures to control access to certificate of analysis data and other testing data to prevent it from being falsified or manipulated.

#### 3.1.2. Certification is granted for specified matrices, technology and analytes.

- A. The CDC will only certify applicants for the matrices, technologies and analytes required for testing under this rule.
- B. The CDC may, at its discretion, allow applicants to submit an application to expand the scope of its certification for one or more of the fields of testing on an individual basis rather than requiring the applicant to meet all fields of testing for all available testing types.
- C. The CDC must conduct a comprehensive on-site inspection of each marijuana/cannabis testing facility prior to granting certification. Following its inspection, the CDC must issue a written initial on-site assessment report which identifies any deficiencies noted during the CDC inspection. In order to receive certification,

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the ~~marijuana~~cannabis testing facility must correct any deficiencies identified and provide documentation of the correction to CDC within 30 days of receipt of the initial on-site inspection report.

**3.1.3. A cannabis testing facility must maintain its CDC certification at all times to remain licensed by DAFS.**

- A. The CDC may, upon reasonable cause, complaint, or to assess continued compliance with this rule, conduct an onsite inspection or review written or electronic records to determine the cannabis testing facility's compliance with the certification requirements described in this section.
- B. Upon the finding of significant or intentional deviation from certification requirements or if the cannabis testing facility refuses to permit access to the site or records, the CDC may suspend or revoke the cannabis testing facility's certification.
  - (1) A cannabis testing facility may not conduct testing of cannabis or cannabis products while its certification is suspended or revoked.
  - (2) The CDC shall communicate any suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.
  - (3) Simultaneously, the CDC shall inform OCP of its actions.
- C. Annual recertification is required.
  - (1) The recertification application shall include at minimum, the following:
    - (a) Any changes to assertions made during initial certification or most recent recertification;
    - (b) Any fines, enforcement or letters of warning by OCP;
    - (c) Copies of updated SOPs;
    - (d) Copy of current QA manual; and
    - (e) Updated copies, at the CDC's discretion, of any materials required for initial certification.
  - (2) The CDC may consider a cannabis testing facility's compliance with certification requirements, proficiency testing, accuracy of testing and reporting implicated in this rule when determining whether to renew the cannabis testing facility's certification.

## Section 3.2 - Quality Assurance Program and Manual

**3.2.1. The cannabis testing facility must develop and implement a quality assurance program.** The program must be sufficient to ensure the reliability and validity of the analytical data produced by the cannabis testing facility. The cannabis testing facility operations must also meet the requirements of the ISO 17025:2017 accreditation.

**3.2.2. The cannabis testing facility must develop and maintain a written quality assurance program manual.**

- A. The manual must contain the following elements:
  - (1) Document title;
  - (2) Identification on each page to ensure that the page is recognized as part of the manual and clear identification of the end of the manual;
  - (3) The cannabis testing facility's name and address;
  - (4) Identification of the cannabis testing facility's approved signatories;
  - (5) A revision number;
  - (6) A date indicating when the revision became effective;
  - (7) A table of contents, applicable lists of references, glossaries and appendices;
  - (8) Listing of all certified testing methods;
  - (9) Relevant organizational charts showing the organization and management structure of the cannabis testing facility and, if applicable, its place within a larger business entity; and

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- (10) Job descriptions of key staff and reference to the job descriptions of other cannabis testing facility staff;
- B. The manual must address all aspects of the cannabis testing facility's quality assurance program, including without limitation the following:
  - (1) Quality control;
  - (2) Quality assurance objectives for measurement data;
  - (3) Traceability of all data, analytical results and certificates of analysis;
  - (4) Equipment preventative maintenance;
  - (5) Equipment calibration procedures and frequency;
  - (6) Performance and system audits;
  - (7) Corrective action;
  - (8) Record retention, including retention of quality assurance records;
  - (9) Document control;
  - (10) Standardization of testing procedures;
  - (11) Method validation;
  - (12) Maintenance, calibration and verification procedures;
  - (13) Major equipment, support equipment and reference measurement standards (e.g., NIST traceable thermometers and weights);
  - (14) Verification practices, which may include proficiency testing programs, use of reference materials, internal quality control processes and inter-cannabis testing facility comparisons;
  - (15) Reporting analytical results and generating the certificate of analysis;
  - (16) Traceability of measurements;
  - (17) Adoption of new testing methods;
  - (18) Handling of samples;
  - (19) Collection and transportation of samples, as applicable;
  - (20) Receipt of samples for mandatory testing, or testing for research and development purposes;
  - (21) Sample rejection;
  - (22) Feedback and corrective action related to testing discrepancies or departures from documented policies and procedures;
  - (23) Policy for permitting departures from documented policies and procedures or from standard specifications;
  - (24) Handling of complaints;
  - (25) Protection of confidentiality and proprietary rights;
  - (26) Data review;
  - (27) Chain of custody forms;
  - (28) Annual internal audits;
  - (29) Evaluation of employee credentials;
  - (30) Employee training, including initial data integrity training for new personnel and annual data integrity training for all current employees with written documentation of attendance;
  - (31) Electronic signatures, where applicable;
  - (32) How data accuracy and precision are determined for each accredited method and analyte within each test category;
  - (33) Disposal of cannabis waste; and
  - (34) Review of all new work to ensure that the cannabis testing facility has appropriate facilities and resources before commencing such work; and
  - (35) Meeting all applicable ISO 17025:2017 accreditation requirements.
- C. The manual may include separate procedures or incorporate documents by reference.

**3.2.3. The quality assurance program and manual must be reviewed and updated regularly to remain current.**

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- A. The facility director and quality assurance officer must review, amend if necessary and approve the quality assurance program and manual.
  - (1) Routine review is required at least annually.
  - (2) The facility director must also review and amend the quality assurance program and manual whenever there is a change in methods, cannabis testing facility equipment or facility director.
  - (3) Documentation of the review process must include the scope of the review, identification and signature of the reviewer and the date the review was completed.
- B. Method detection limits and reporting limits may be determined by methods used by the U.S. Environmental Protection Agency.
  - (1) The cannabis testing facility may use the procedure for determining the method detection limit described in 40 C.F.R. Part 136, Appendix B, revised as of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017; or
  - (2) Other methods published by the federal U.S. Food and Drug Administration for the determination of limit of detection (LOD) and limit of quantitation including Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, April 2015.

### Section 3.3 - Standard Operating Procedures (SOPs).

**3.3.1. Written SOPs are required.** The cannabis testing facility must possess written SOPs used by cannabis testing facility personnel for the analysis of samples and must prepare written procedures for all cannabis testing facility activities, including, but not limited to, sample collection, sample acceptance, sample analysis, operation of instrumentation, generation of data and performance of corrective action.

- A. Only the facility director, quality assurance officer or designee may make changes to SOPs.
- B. Such changes are effective only when documented in writing and approved by the facility director or quality assurance officer.
- C. The SOPs must be formatted to include:
  - (1) A table of contents;
  - (2) A unique identification of the SOP, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the manual and a clear identification of the end of the manual;
  - (3) Page numbers;
  - (4) The cannabis testing facility's name;
  - (5) A revision number; and
  - (6) A date indicating when the revision became effective.
- D. Each analytical method SOP must include or reference the following topics, where applicable:
  - (1) Identification of the method;
  - (2) Applicable matrix or matrices;
  - (3) Limits of detection and quantitation;
  - (4) Scope and application, including parameters to be analyzed;
  - (5) Summary of the method;
  - (6) Definitions;
  - (7) Interferences;
  - (8) Safety;
  - (9) Equipment and supplies;
  - (10) Reagents and standards;
  - (11) Sample collection, preservation, shipment and storage;
  - (12) Quality control (QC);
  - (13) Calibration and standardization;

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- (14) Procedure;
  - (15) Data analysis and calculations;
  - (16) Method performance;
  - (17) Pollution prevention;
  - (18) Data assessment and acceptance criteria for QC measures;
  - (19) Corrective actions for out-of-control data;
  - (20) Contingencies for handling out-of-control or unacceptable data;
  - (21) Waste management;
  - (22) References; and
  - (23) Any tables, diagrams, flowcharts and validation data.
- E. For pesticide analysis, the SOP must include established and documented detection limits for each matrix type.

### 3.3.2. Written SOPs are requirements of certification and licensing and must be followed.

- A. Actual practice must conform to the written procedures.
  - (1) The [cannabis](#) testing facility must maintain copies of the methods from which the procedures are developed and must ensure that the applicable requirements are incorporated into each procedure.
  - (2) A copy of each procedure must be available to all personnel that engage in that activity.
  - (3) An analyst must use the [cannabis](#) testing facility's SOP beginning on its effective date.
- B. Standard operating procedure requirements may be considered confidential material, and [OCP](#) and the CDC may not disclose the information except in conjunction with agency actions.
- C. The [cannabis](#) testing facility must maintain a record of effective dates for all procedures and must review SOPs at least annually. A copy of the procedure and the record of effective dates must be maintained for the same period that records of the data generated by those procedures are required to be maintained.
- D. The [cannabis](#) testing facility must keep all standard operating procedures on the [cannabis](#) testing facility premises and in the field, as necessary, and must ensure that each standard operating procedure is accessible to [cannabis](#) testing facility personnel during operating hours. The [cannabis](#) testing facility must make the standard operating procedures available to the CDC upon request.
- E. All changes to the SOPs must be documented.
  - (1) Changes to the SOPs must be incorporated at least annually.
  - (2) The [cannabis](#) testing facility's facility director must review, approve, sign and date each SOP and each revision to a SOP.
  - (3) The SOPs must include the dates of issue and dates of revision, if any.

## Section 3.4 - Proficiency Testing

The [cannabis](#) testing facility must participate in a proficiency-testing program provided by an ISO-17043-accredited proficiency test provider, at least annually each year. The CDC may waive proficiency testing requirements if no proficiency tests are available.

### 3.4.1. Proficiency tests are required.

- A. Any [cannabis](#) testing facility seeking to obtain certification must successfully complete at least one proficiency test sample for each requested field of testing.

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- (1) The proficiency test must occur within six months prior to the date that the cannabis testing facility submits its initial application, and annually thereafter
  - (2) When any cannabis testing facility is granted certification, it must continue to complete proficiency testing studies for each field of testing and maintain a history of at least one acceptable evaluation for each field of testing out of the most recent two proficiency test sample results submitted to the proficiency test provider.
  - (3) To maintain certification, the cannabis testing facility must complete the annual study, and any corrective action study required, each year.
  - (4) Failure to participate in a proficiency test may result in disciplinary action against the cannabis testing facility, including suspension or revocation of certification.
- B. Proficiency testing must be conducted according to the following guidelines:
- (1) The cannabis testing facility must rotate the proficiency tests among cannabis testing facility staff, so that all methods and all staff performing the methods have participated in proficiency tests over a reasonable planned period, as defined in the cannabis testing facility quality assurance manual.
  - (2) The cannabis testing facility must analyze the proficiency test samples following the approved cannabis testing facility standard operating procedures and using the same equipment that are used for testing.
  - (3) Cannabis testing facility employees who participate in a proficiency test must sign corresponding analytical reports or attestation statements to certify that the proficiency test was conducted in the same manner as the cannabis testing facility ordinarily conducts testing.
  - (4) The facility director must review and approve all proficiency test samples analyzed and results reported.
  - (5) The cannabis testing facility must authorize the proficiency test provider to release the results of the proficiency test to OCP and CDC at the same time that the results are submitted to the cannabis testing facility.
  - (6) Prior to the closing date of a study, cannabis testing facility personnel, including corporate personnel, may not:
    - (a) Communicate with any individual at another cannabis testing facility, concerning the analysis of the proficiency test sample prior to the closing date of the study;
    - (b) Subcontract the analysis of any proficiency test sample or a portion of a proficiency test sample to another cannabis testing facility for any analysis;
    - (c) Knowingly receive and analyze any proficiency test sample or portion of a proficiency test sample from another cannabis testing facility, for which the results of the proficiency test sample are intended for use for initial or continued certification; or
    - (d) Attempt to obtain the assigned value of any proficiency test sample.
  - (7) The cannabis testing facility must analyze proficiency test samples in the same manner used for routine samples, using the same staff, sample tracking, sample preparation and analysis methods, SOPs, calibration techniques, QC procedures and acceptance criteria.
  - (8) The cannabis testing facility must follow sample preparation steps for the proficiency test sample, as instructed by the approved proficiency test provider for which the proficiency test sample was obtained.
  - (9) Testing facilities under the same ownership may not participate in the same study by the same approved proficiency test provider for the same fields of testing, except when a study is not again available for that field of testing by any approved proficiency test provider within the calendar year.
- C. Errors in reporting the proper matrix, the method used or the tested analytes in the proficiency test study by the cannabis testing facility must be graded as “not acceptable.”

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#### 3.4.2. Cannabis testing facilities must provide proficiency test results.

- A. The cannabis testing facility must evaluate and report the analytical result for certification as follows:
  - (1) For instrument technology that employs a multi-point calibration, the working range of the calibration under which the proficiency test sample is analyzed must be the same range as used for routine samples.
    - (a) A result for any proficiency test at a concentration above or equal to the lowest calibration standard must be reported as the resultant value.
    - (b) A result for any proficiency test at a concentration less than the lowest calibration standard must be reported as less than the value of the lowest calibration standard.
    - (c) A result for any proficiency test greater than the highest calibration standard must be diluted to fall within the range of the calibration curve.
  - (2) For instrument technology that employs standardization with a zero point and a single point calibration standard, the cannabis testing facility must evaluate the analytical result in the same range as used for routine samples.
    - (a) A result for any proficiency test at a concentration above or equal to the reporting limit must be reported as the resultant value.
    - (b) A result for any proficiency test at a concentration less than the reporting limit must be reported as less than the value of the reporting limit.
    - (c) A result for any proficiency test greater than the high calibration standard must be diluted to be within the working range.
- B. The cannabis testing facility must ensure that the proficiency test results include the correct physical address of the cannabis testing facility.
- C. The cannabis testing facility must report the analytical results to the proficiency test provider on or before the closing date of the study using the reporting format specified by the proficiency test provider.
- D. On or before the closing date of the study, the cannabis testing facility must authorize the proficiency test provider to release the cannabis testing facility's final evaluation report directly to OCP and the CDC.
- E. The cannabis testing facility must supply results by authorizing the approved proficiency test provider to release all PT results and corrective action results to the certification officer by an electronic format specified by the certification officer. The CDC must evaluate only results received directly from the proficiency test provider.
- F. The cannabis testing facility may not request a revised report from the proficiency test provider, when the revisions to the report are due to any error on the part of the cannabis testing facility.

#### 3.4.3. Successful performance is required.

- A. The cannabis testing facility must successfully participate in a proficiency test for each matrix, technology and analyte.
  - (1) Test results are considered "satisfactory" for an analyte tested in a specific technology, or if the results demonstrate a positive identification of an analyte tested in a specific technology, including quantitative results, when applicable.
  - (2) A cannabis testing facility must analyze only the analytes for which proficiency test results were considered "satisfactory."
  - (3) The reporting of a false-positive result is an "unsatisfactory" score for the proficiency test.
- B. The cannabis testing facility must take corrective action and document corrective action, when the cannabis testing facility fails to score 100% on a proficiency test.
  - (1) Within 30 days of receiving an "unacceptable," "questionable," or "unsatisfactory" proficiency test result, a cannabis testing facility must submit the proficiency-test results and detailed corrective action responses to the CDC.

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- (a) This information must include root-cause analysis and remedial action plans.
  - (b) The cannabis testing facility must not accept samples or analyze the analytes for which proficiency test results were considered “unacceptable,” or “unsatisfactory,” until completing the corrective action and resolving the problem.
  - (c) The cannabis testing facility must enroll in the next available round of proficiency tests.
  - (d) Such enrollment should be documented in the corrective action plan initiated in response to a proficiency test failure.
- (2) The cannabis testing facility may not continue to report results for analytes that were deemed “unacceptable,” “questionable” or “unsatisfactory” if the cannabis testing facility has two successive failed proficiency test studies for any analyte and technologies.
  - (3) Within 180 days of an unacceptable or unsatisfactory proficiency test result, the cannabis testing facility must submit a written report showing whether the cannabis testing facility successfully implemented the corrective action to the CDC.
  - (4) Within 30 days of receipt of a corrective action report, the cannabis testing facility must order a new proficiency test to demonstrate proficiency for reinstatement of certification.
- C. If the facility fails two successive proficiency test studies for any analyte and technology, certification for that analyte and technology is suspended immediately. Certification may be reinstated pending successful completion of two successive proficiency test studies.

#### **3.4.4. Proficiency test sample study records must be maintained.**

- A. The cannabis testing facility must maintain copies of all written, printed and electronic records pertaining to proficiency test sample analyses for 5 years.
- B. Proficiency test records must include, without limitation:
  - (1) Bench sheets;
  - (2) Instrument strip charts or printouts;
  - (3) Data calculations;
  - (4) Data reports; and
  - (5) Proficiency test study report forms used by the cannabis testing facility to record proficiency test results.
- C. The cannabis testing facility must make all retained records available to cannabis certification officers during on-site assessments of the cannabis testing facility.

### **Section 3.5 - Conducting Annual Internal Audit**

- A. The cannabis testing facility must conduct an internal audit at least once per year, or per the ISO/IEC 17025:2017 or most recent version accrediting body’s requirement, whichever is more frequent.
- B. The internal audit must cover everything required to be covered by this Rule and ISO/IEC 17025:2017 or most recent version internal-audit standards.
- C. The internal audit will be reviewed during the on-site assessment by the CDC, during an inspection by the CDC, or at the request of the CDC.
- D. Failure to conduct an internal audit or failure to submit the results of an internal audit to the CDC may subject the cannabis testing facility to suspension or revocation of certification.

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## Section 4 – Required Cannabis Testing Facility Personnel, Training and Supervision

### Section 4.1 - Required Personnel

Certification requires a cannabis testing facility to employ a qualified facility director and sufficient cannabis testing facility analysts and staff to handle the anticipated volume of testing. The cannabis testing facility must either employ a qualified quality assurance officer (QAO) or designate the facility director to fulfill that role. The cannabis testing facility must ensure that a testing facility director or QAO meeting the requirements of this rule is onsite and available during the hours of operation indicated on the facility's operating plan.

#### 4.1.1. General requirements.

- A. All management of the cannabis testing facility and performance of required testing and related activities must be performed by personnel who meet the required educational and experience requirements.
- B. Only degrees issued by, or courses completed at, an accredited college or university may fulfill the educational requirements of this section.
- C. To meet practical laboratory experience requirements, prior work experience must:
  - (1) Have involved full-time work of 30 or more hours per week;
  - (2) Not have been completed as part of any educational requirement, even if it did not lead to the conferring of a degree; and
  - (3) Have taken place in a laboratory or cannabis testing facility performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

#### 4.1.2. Facility director.

- A. To be a facility director of a certified cannabis testing facility under this rule, a person must meet one of the following:
  - (1) A doctoral degree in a related science and 1 year of practical laboratory experience;
  - (2) A master's degree in a related science and 2 years of practical laboratory experience; or
  - (3) A bachelor of science or bachelor of art degree in a related science and 4 years of practical laboratory experience.
- B. The facility director must be capable of fulfilling all the following core responsibilities:
  - (1) Oversee and direct the scientific methods of the cannabis testing facility;
  - (2) Ensure that the cannabis testing facility achieves and maintains quality standards of practice;
  - (3) Supervise all personnel; and
  - (4) Be present in the cannabis testing facility an average of 60% of hours of operation.
- C. The facility director may not have been convicted of an offense punishable by 1 year or more in prison and related to conduct involving dishonesty, fraud, deceit or gross negligence with the intent to substantially benefit himself, herself or another or to substantially injure another.
- D. The testing facility must appoint a deputy when the testing facility director is absent from the testing facility for more than 15 consecutive calendar days.
  - (1) The deputy facility director must meet the qualifications for testing facility director or QAO.
  - (2) Testing facility management must notify OCP and CDC in writing when the absence of the testing facility director is expected to, or in fact exceeds, 60 consecutive calendar days.
- E. Any requests for a waiver of any provision under this paragraph must be submitted in writing to the CDC, which reserves the right to deny such a request.

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#### 4.1.3. Quality assurance officer (QAO).

- A. To be a QAO of a certified cannabis testing facility under this rule, a person must satisfy one of the following:
  - (1) Meet the qualification criteria required for a facility director; or
  - (2) Hold a bachelor's degree in one of the related sciences; or
  - (3) Have completed at least 2 years of college coursework and at least 1 year of practical laboratory experience.
- B. The QAO must be capable of fulfilling all the following core responsibilities:
  - (1) Ensure that the cannabis testing facility achieves and maintains quality standards of practice;
  - (2) Review cannabis testing facility quality control data, conduct annual internal audits, notify management of deficiencies found in the quality system, ensure the accuracy and integrity of certificates of analysis and be free from internal and external influences, when evaluating data and conducting audits;
  - (3) Provide documented training and/or experience in QA and QC procedures and demonstrate knowledge of the approved analytical methods and quality system requirements, as well as maintain the QA documents up to date;
  - (4) Have direct access to cannabis testing facility management; and
  - (5) Whenever possible, conduct functions that are independent from the cannabis testing facility operations for which they have quality assurance oversight.
- C. The QAO, regardless of other duties and responsibilities, must have defined responsibility and authority for ensuring that the management system related to quality and integrity of testing results is implemented and complied with at all times.
- D. The QAO duties and responsibilities may alternatively be carried out by the cannabis testing facility technical director.

**4.1.4. Cannabis Testing Facility Analyst.** Any person who performs analytical tasks must meet the experience and educational requirements of an analyst and must be able to demonstrate proper performance of all analytical tasks. To be an analyst employed by a certified cannabis testing facility pursuant to this Rule, a person must meet one of the following standards:

- A. Fulfill the qualification criteria required for the facility director; or
- B. Hold a bachelor's degree in one of the related sciences; or
- C. Demonstrate completion of at least 2 years of college coursework and at least 1 year of practical laboratory experience.

**4.1.5 Cannabis Testing Facility Sample Collection.** If the cannabis testing facility offers sample collection services, any person who performs sample collection for a cannabis testing facility must meet the experience and educational requirements of a sample collector contained in Section 5.1.5 of this Rule and be able to demonstrate appropriate sampling methods.

## Section 4.2 - Verification and Maintenance of Personnel Documentation

The cannabis testing facility must verify and maintain documentation of qualifications of all employees and contracted workers. Required documentation includes the following:

- A. Documentation of the employee's education:
  - (1) The colleges and universities attended by the employee and the names and addresses of the colleges and universities, the major course of study, dates of attendance, degrees conferred and completion date;

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- (2) Official transcripts from the registrar of the colleges and universities attended by the employee showing all courses, course credits, degrees conferred, and dates degrees were conferred; and
- (3) Records from credential evaluation services, including translations of transcripts from non-English-language colleges and universities. For an employee who attended a college or university not located in the United States (U.S.) or its territories, the requirement that the college or university be accredited is satisfied if the educational credentials of the employee are found, by the credential evaluation service, to be equivalent to those of a person who attended an accredited U.S. college or university.
- B. Documentation of each employee's experience:
  - (1) Name and address of the laboratory or cannabis testing facility where the employee received non-course related experience, dates of employment, number of hours per week employed and a description of the testing and analytic methods performed by the person; and
  - (2) Signed documentation of such experience from the director or equivalent of the laboratory or cannabis testing facility.
- C. Records of all individual identification cards including the identification number and the date of issuance and expiration for every principal office, board member and employee of the cannabis testing facility.
- D. Personnel plans reflecting sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. cannabis testing facility management must:
  - (1) Specify and document the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests;
  - (2) Establish job descriptions to include the minimum level of qualifications, experience and basic cannabis testing facility skills necessary for all positions in the cannabis testing facility;
  - (3) Document authority of specific personnel to perform particular types of sampling and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
  - (4) Document authority of specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.
- E. Records of the relevant authorization(s), demonstration(s) of capability, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information must be readily available and include the date on which authorization and/or competence is confirmed.
- F. Documentation of the initials and signatures of anyone analyzing or reviewing data so that the records can be traced back to the individual approving the data.

### Section 4.3 - Personnel Training and Supervision

The cannabis testing facility management must:

- A. Provide adequate supervision of staff by persons familiar with methods and procedures;
- B. Formulate goals with respect to the education and training skills of the cannabis testing facility personnel, including:
  - (1) Policies and procedures for identifying training needs and providing training of personnel;
  - (2) Ensuring relevance of the training program to the present and anticipated tasks of the cannabis testing facility; and
  - (3) Making documentation available upon request from the CDC;
- C. Ensure all technical cannabis testing facility staff has demonstrated capability in the activities for which they are responsible; and
- D. Ensure that the training of the cannabis testing facility personnel is kept up to date (on-going) by providing the following:

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- (1) Documentation that each employee has read, understands and uses the latest version of the cannabis testing facility's quality documents and security plan;
- (2) Training documentation on equipment, techniques and/or procedures;
- (3) Training in ethical and legal responsibilities; and
- (4) Documentation of each analyst's continued performance at least once per year.

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## Section 5 – Samples for Testing and Research

A [cannabis](#) testing facility may offer a service to collect samples for mandatory testing from a licensee. A [cannabis](#) testing facility may contract with or otherwise accept samples for mandatory testing from a sample collector licensed pursuant to Title 28-B and 18-691 CMR, ch. 1. A [cannabis](#) testing facility may accept samples for mandatory testing from a self-sampling licensee authorized to collect samples pursuant to Title 28-B and 18-691 CMR, ch. 1. All samples for mandatory testing must be collected in accordance with Title 28-B, 18-691 CMR, ch. 1 and this Rule.

### Section 5.1 – Samples for Mandatory Testing or Research and Development

**5.1.1. Authorized collection of samples.** In accordance with 28-B MRS §§604 and 604-A, all samples for mandatory testing under this Rule must be collected by:

- A. An employee of the testing facility;
- B. A licensed sample collector; or
- C. A self-sampling licensee, collecting samples of [cannabis](#) or [cannabis](#) products cultivated, manufactured or otherwise produced by that licensee in compliance with all requirements of 18-691 CMR, ch. 1.

**5.1.2. Collection by [cannabis](#) testing facilities or sample collectors.** An employee of a [cannabis](#) testing facility or a sample collector must collect samples of [cannabis](#) or [cannabis](#) products in compliance with:

- A. Sample collection recordkeeping requirements of 18-691 CMR, ch. 1;
- B. The Department-required sampling standard operating procedures;
- C. The Department-required Best Practices Guide;
- D. The requirements and restrictions of 28-B MRS § 604; and
- E. The requirements and restrictions of 18-691 CMR, ch. 1.

**5.1.3. Collection by self-sampling licensees.** A self-sampling licensee may collect samples of [cannabis](#) or [cannabis](#) products cultivated, manufactured, or otherwise produced or sold by that licensee if the licensee has submitted all required documentation to the Department and in compliance with:

- A. Sample collection recordkeeping requirements of 18-691 CMR, ch.1;
- B. The Department-required sampling standard operating procedures;
- C. The Department-required Best Practices Guide;
- D. The requirements and restrictions of 28-B MRS § 604-A; and
- E. The requirements and restrictions of 18-691 CMR, ch. 1.

**5.1.4. Required documentation and record keeping.** An adult use [cannabis](#) cultivation, manufacturing, or [cannabis](#) store licensee requesting testing by a [cannabis](#) testing facility must indicate in its request for testing whether the requested testing is for mandatory testing purposes as required by 18-691 CMR, ch. 1, or for research and development purposes. The licensee must indicate in writing, prior to collection of the samples for testing, whether such testing is for mandatory testing purposes or for research and development purposes.

- A. Pursuant to 28-B MRS § 602(2), a licensee must maintain a record of all mandatory testing conducted at the request of the licensee that includes at a minimum:
  - (1) A description of the [cannabis](#), [cannabis](#) concentrate or [cannabis](#) product submitted for mandatory testing;
  - (2) The identity of the testing facility conducting the mandatory testing; and

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- (3) The results of any and all mandatory testing conducted at the request of the licensee.

**5.1.5. Qualifications.** Employees of a [cannabis](#) testing facility or sample collectors who collect samples from licensees must have a current individual identification card issued by [OCP](#) and must:

- A. Be physically able to perform the duties, with or without reasonable accommodations;
- B. Pass initial and ongoing demonstrations of capability;
- C. When available, complete 8 hours of initial training on various sampling techniques; and
- D. When available, complete 8 hours of periodic refresher training annually.

**5.1.6. Transportation of Samples.** A sample collector or self-sampling licensee may transport a sample from a licensee to the [cannabis](#) testing facility for testing and analysis.

- A. The sample collector or self-sampling licensee shall ensure the samples are not visible to the public. Samples shall be locked in a fully enclosed box, container or cage that is secured to the inside of the vehicle or trailer. For the purposes of this section, the inside of the vehicle includes the trunk.
- B. The sample collector or self-sampling licensee shall ensure that packages or containers holding [cannabis](#) goods samples are neither tampered with nor opened during transport.
- C. An employee of a [cannabis](#) testing facility who is collecting samples of [cannabis](#), [cannabis](#) concentrate or [cannabis](#) products for mandatory testing shall only travel between licensees for whom the [cannabis](#) testing facility is conducting mandatory testing and the [cannabis](#) testing facility's premises when engaged in the transportation of samples; a sample collector not employed by a [cannabis](#) testing facility shall only travel between licensees for whom the sample collector is collecting samples and the [cannabis](#) testing facility(ies) conducting the mandatory testing. A sample collector shall not deviate from the travel requirements described in this section, except for necessary meals or rest required by law, or refueling.
- D. The sample collector may transport multiple samples obtained from multiple licensees at once. A self-sampling licensee may transport only those samples collected by the licensee and must deliver those samples to the [cannabis](#) testing facility directly.
- E. Only persons who are in possession of a valid individual identification card issued by [OCP](#) may be in a vehicle or trailer transporting samples.
- F. All samples being transported must have a label with the following statement: "For Testing Purposes Only."

## Section 5.2 – Protocols for Acceptance of Samples Collected by Licensees or Other Qualified Persons

The [cannabis](#) testing facility must develop and maintain a plan for receiving samples for mandatory and other testing.

**5.2.1. SOPs.** If the [cannabis](#) testing facility accepts samples from a sample collector or self-sampling licensee for mandatory or other testing, it must develop and maintain SOPs for receiving samples.

- A. A sample collector or self-sampling licensee must contact the [cannabis](#) testing facility(ies) and comply with the [cannabis](#) testing facility's recommendations, based upon matrices sampled and analyses required, regarding, without limitation:
  - (1) Sample collection tools;
  - (2) Sample collection and transport containers;
  - (3) Whether any Field or Trip blanks are required to be collected, transported or otherwise used or delivered to the [cannabis](#) testing facility pursuant to the [cannabis](#) testing facility's quality system; and
  - (4) Any limitations regarding sample delivery.

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- B. The SOPs must have detailed chain of custody protocols for receiving samples.
- C. The SOPs must require sample collectors or self-samplers to address factors such as storage, environmental conditions, transportation of the batch or sample, tamper evident sealing and labeling samples for transport “For Testing Purposes Only.”
- D. The SOPs must address representativeness of the samples received from the sample collector or self-sampler; the sampling increments must be selected at random by the sample collector or self-sampler, and designed so that the samples collected reflect the total composition of the product.
- E. The SOPs must be designed to meet specified sample quality criteria, which is dependent upon whether the samples provided are for mandatory testing in compliance with the requirements of Title 28-B, ch. 1 or additional analyses not required by law. For non-mandatory test samples, this requires a sampling plan that includes enough representative sample increments to meet the client-specified confidence intervals.
- F. The SOPs must address volume of sample to be collected by sample collector or self-sampler from each batch in compliance with the requirements of Section 6 of this rule for samples collected for mandatory testing, or client specifications for non-mandatory testing. This specification will ensure that adequate sample volume is collected for the analyses required, including all required quality control samples and any potential confirmation analysis.

## Section 5.3 – Chain of Custody and Document Control Requirements

Testing facilities must develop and implement a chain of custody protocol to ensure accurate documentation of the handling, storage and destruction of cannabis samples. All samples for mandatory testing must also be accompanied by any documentation required by the testing facility.

**5.3.1. Chain of custody forms.** The chain of custody protocol must require the use of a chain of custody form that contains, at a minimum, the following:

- A. Cannabis testing facility name, physical address and certification number of the cannabis testing facility analyzing the sample;
- B. Requester name, physical address and license or registration number; or if a registered caregiver, the registration card identification number; or if an exempt caregiver, the caregiver’s name and address; or if a qualifying patient, the patient’s name and address;
- C. Information regarding each primary sample, as follows:
  - (1) Unique primary sample identifier, as indicated on the sample container;
  - (2) For sample increments from the same sampled batch that are separated for homogeneity testing, the unique sample increment identifier as indicated on the container holding the separate sample increment for homogeneity testing;
  - (3) The sample location, number and type of containers used to collect samples, and the sample collection technique(s) used to collect the samples;
  - (4) Date and time of the sample collection;
  - (5) The printed names and signatures of the sample collector(s);
  - (6) For cannabis products that need to be stored at specific temperatures: All conditions, including sample temperature at time of collection and temperature of the cooler used for transport; and
  - (7) The printed name and signature of the person at the cannabis testing facility receiving the samples
  - ~~(8)(7) The location of the sample within the marijuana cannabis testing facility storage area.~~

### 5.3.2. Document control.

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- A. Each time the sample changes custody, is transported, is removed from storage at the [cannabis](#) testing facility, or is destroyed, the date, time and the names and signatures of persons involved in these activities must be recorded on the chain of custody form.
- B. All documents must be controlled and retained in accordance with this rule.
  - (1) A complete chain of custody is required for each batch.
  - (2) If there is a quality assurance plan for the client, the sampling plan can be abbreviated to include the client and [cannabis](#) testing facility information and any variation or modification that occurred in the sampling event.

## Section 5.4 - Sample Rejection

- A. When samples are received by the [cannabis](#) testing facility, the [cannabis](#) testing facility must check the integrity of the samples. The [cannabis](#) testing facility must deem a sample compromised if one or more of the following has occurred:
  - (1) Broken shipping container;
  - (2) Evidence that the sample has been tampered with, manipulated, adulterated or contaminated;
  - (3) Evidence that the sample was not collected in the manner required by this rule or the DAFS-required sample collection SOP;
  - (4) Any missing or incomplete sample collection records required by testing facility in accordance with its quality system;
  - (5) The temperature of the sample is out of the required range to prevent microbial growth;
  - (6) The sample weight, as determined upon receipt by the [cannabis](#) testing facility, is greater than +/- 10% difference than the weight recorded on the transport manifest accompanying the samples; or
  - (7) Any other factor that may have negatively impacted the integrity of the sample since its collection.
- B. If the sample is rejected, the [cannabis](#) testing facility must document the sampling or handling errors, contact the requester and the sample collector (if the requester did not self-sample), schedule re-sampling and time for sample receipt, and document the conversation with all parties, including any additional specific instructions given to the sampling party to correct any sample deficiencies noted.

## Section 5.5 - Sample Collection

### 5.5.1. Sample Collection by [Cannabis](#) Testing Facility Personnel.

- A. At minimum, the [cannabis](#) testing facility must use the *Maine Adult Use [Cannabis](#) Program Sample Collection Standard Operating Procedure for Mandatory Testing* included as Appendix A to the *Adult Use [Cannabis](#) Program Rule*, 18-691 CMR, ch.1, and must complete for every batch a sample collection record to ensure it is collecting samples that support accurate analyses of cannabinoids, residual solvents and processing chemicals, contaminants, pesticides, microbiological impurities, mycotoxins, water activity, filth and foreign material and heavy metals, in compliance with *Best Practice Guide for the Sample Collection of Adult Use [Cannabis](#) for Mandatory Testing* published by DAFS.
- B. The [cannabis](#) testing facility must collect adequate samples of the [cannabis](#), [cannabis](#) concentrate or [cannabis](#) product in the form in which it will be conveyed to a consumer (finished or unfinished plant material; [cannabis](#) concentrate; or an unpackaged or pre-packaged [cannabis](#) product) in accordance with Table 5.5-A. The sample must comprise the number of sample increments, selected at random, indicated in Table 5.5-A. The [cannabis](#) testing facility will combine these increments to make one complete sample for testing.

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**Table 5.5-A. Required Sample Size Based Upon Matrix Type and Batch Size**

Matrix Type	Harvest Batch Weight Range*	Production Batch Units*	Primary Sample Amount
Plant Material	≤ 2.5 kg		6.5 g (13 increments of 0.5 grams each)
	2.5 kg < w ≤ 5 kg		9.5 g (19 increments of 0.5 grams each)
	5 kg < w ≤ 7.5 kg		16 g (16 increments of 1 gram each)
	7.5 kg < w ≤ 10 kg		22 g (22 increments of 1 gram each)
Concentrate	≤ 0.5 kg		6 g (12 increments of 0.5 grams each)
	0.5 kg < w ≤ 1 kg		8 g

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			(16 increments of 0.5 grams each)
	1 kg < w ≤ 1.5 kg		10 g (20 increments of 0.5 grams each)
	1.5 kg < w ≤ 2 kg		12 g (24 increments of 0.5 grams each)
	2 kg < w ≤ 5 kg		14 g (28 increments of 0.5 grams each)
<b>Product **</b>		≤ 50	2 units
		51 -150	3 units
		151 - 500	5 units
		501-1200	8 units
		1201 -3200	13 units
		3201-10000	20 units

\*For harvest or production batches in excess of the sizes listed in this table (10 kg of plant material, 5 kg of concentrate or 10,000 production batch units), the batch must be divided and sampled in smaller batches in accordance with the batch size limits listed in this table, the requirements of this Rule, and the requirements of 18-691 CMR, ch. 1.

\*\*For production batches of prepackaged [marijuanacannabis](#) products, one production unit is one sample increment. For production batches of unpackaged [marijuanacannabis](#) products, one serving size of the [marijuanacannabis](#) product is one sample increment.

#### 5.5.2. Sample Collection by Sample Collectors and Self-Samplers.

- A. Sample collectors and self-samplers must collect samples of [marijuanacannabis](#), [marijuanacannabis](#) concentrate and [marijuanacannabis](#) products in accordance with [OMPOCP's Maine Adult Use Marijuana Cannabis Program Sample Collection Standard Operating Procedure for Mandatory Testing](#) and must complete for every batch a sample collection record in accordance with 18-691 CMR, ch.1, §3.11, in addition to any additional forms, including chain of custody forms, required by the [marijuanacannabis](#) testing facility receiving the samples.
- B. Sample collectors and self-samplers must collect the required number of sample increments, based upon matrix type and batch size, in accordance with Table 5.5-A. The sample collector or self-sampler will specify in its sample collection records, after contacting the [marijuanacannabis](#) testing facility, the number and type of sample containers required to transport the primary sample and any separate sample increments to the testing facility for mandatory testing.

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- a. Sample increments for homogeneity testing must be stored in a separate sample collection container from the other combined primary sample to ensure accurate testing.
- b. Sample increments for some analyses, depending on the instrumentation of the cannabis testing facility conducting the mandatory analyses, may require storage and transport in particular kinds of sample collection containers to ensure the integrity of the samples collected.

## Section 5.6 - Sample Preparation and Testing

- A. The cannabis testing facility must designate an area for preparation of cannabis product samples for analysis.
- B. The preparation area must include:
  - (1) Disposable gloves to be worn, to avoid sample contamination;
  - (2) Decontaminated or single-use disposable tool(s), including stainless steel spatulas, knives and/or disposable pipettes;
  - (3) Decontaminated stainless-steel bowls and implements for homogenizing samples appropriately;
  - (4) Clean, decontaminated surfaces for sample processing;
  - (5) Decontaminated or single use, disposable sample containers appropriate for processing;
  - (6) Labels and pens with indelible ink; and
  - (7) Necessary supplies for thoroughly cleaning, decontaminating and drying sample preparation tools and equipment between samples.
- C. The cannabis testing facility shall ensure that any primary samples of cannabis flower or cannabis trim, including pre-rolled cannabis cigarettes and infused pre-rolled cannabis cigarettes, are homogenized in accordance with the following requirements:
  - (1) The cannabis testing facility shall first remove any sample increments required to conduct testing for microbials and water activity; and
  - (2) The cannabis testing facility shall then homogenize, by grinding or other suitable method, the entirety of the remaining sample material, including any stems, seeds, or fan leaves submitted in the primary sample.
  - (3) Any cannabis testing facility retesting of a portion of the original sample must be taken from the same homogeneous material of the original primary sample.
  - (4) Retesting of the original sample material by the cannabis testing facility may only be done to investigate instrument malfunctions or sample handling problems such as dilution errors. In the case of a clearly identified cannabis testing facility error, the retest results must substitute for the original test result.

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## Section 6 – Testing of Cannabis and Cannabis Products

### Section 6.1 - Mandatory Testing Required

An adult use cannabis licensee may not sell or distribute adult use cannabis or an adult use cannabis product to a cannabis store for sale to a consumer unless the cannabis or cannabis product has been tested pursuant to this Rule and that mandatory testing has demonstrated that the cannabis or cannabis product does not exceed the maximum level of allowable contamination for any contaminant that is injurious to health and for which testing is required, except that OCP may temporarily waive mandatory testing requirements under this section for any contaminant or factor for which OCP has determined that there exists no licensed cannabis testing facility in the state capable of and certified to perform such testing. It is the responsibility of the licensee transferring cannabis or cannabis products to a cannabis store licensee for sale to consumers to ensure that the cannabis or cannabis products have passed all mandatory testing required by this rule prior to transfer to the cannabis store licensee.

### Section 6.2 - Mandatory Testing and Additional Analysis

Cannabis and cannabis products must be tested in accordance with this Rule. OCP or a client may request additional analyses which will be specified by the cannabis testing facility in the written sampling plan.

- A. The following tests are mandatory for all cannabis or cannabis products, except seedlings, immature cannabis plants and seeds, prior to being transferred to a cannabis store for sale to a consumer:
- (1) **Filth and foreign material.** Any visible contaminant, including without limitation hair, insects, feces, mold, sand, soil, cinders, dirt, packaging contaminants and manufacturing waste and by-products.
  - (2) **Residual solvents, poisons and toxins.** Acetone, acetonitrile, butane, ethanol, ethyl acetate, ethyl ether, heptane, hexane, isopropyl alcohol, methanol, pentane, propane, toluene, total xylenes (m, p, o-xylenes), 1,2-dichloroethane, benzene, chloroform, ethylene oxide, methylene chloride, trichloroethylene and any others used. A cannabis testing facility is not required analyze for residual solvents and processing chemicals in dried flower, kief, hashish or cannabis products manufactured without chemical solvents. A cannabis testing facility is not required to analyze an orally-consumed tincture containing alcohol for residual ethanol. A licensee is not required to test a cannabis product for residual solvents, poisons and toxins if all cannabis concentrate used to make the cannabis product has previously passed mandatory testing for residual solvents.
  - (3) **Pesticides (insecticides, fungicides, herbicides, acaricides, plant growth regulators, disinfectants, etc.).** Any pesticide, insecticide, fungicide, herbicide, acaricide, plant growth regulator, disinfectant or Any pesticide, insecticide, fungicide, herbicide, acaricide, plant growth regulator, disinfectant or any other chemical included as a pesticide in Table 6.8-A. A licensee is not required to test a cannabis concentrate or a cannabis product for pesticides, fungicides, insecticides and growth regulators if all cannabis flower and/or trim used to make the cannabis concentrate or cannabis product has previously passed mandatory testing for pesticides, fungicides, insecticides and growth regulators.
  - (4) **Other harmful chemicals.** Cadmium (Cd), lead (Pb), arsenic (As) and mercury (Hg), and any other additives or ingredients determined to be harmful to human health. A licensee is not required to test a cannabis product for the other harmful chemicals listed herein if the cannabis

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- concentrate used to make the cannabis product has previously passed mandatory testing for the other harmful chemicals listed herein.
- (5) **Dangerous molds and mildew.** Total yeast and mold, and for any cannabis or cannabis product that fails an initial test for total yeast and mold, mycotoxins including aflatoxins (B1, B2, G1, and G2) and ochratoxin A.
- (5)
- (6) **Harmful microbes.** Total viable aerobic bacteria, total coliforms, Enterobacteriaceae, *E. coli* (STEC) and Salmonella (spp.).
- (7) **THC potency, homogeneity and cannabinoid profiles.** THC and any other cannabinoid to be referenced in labeling or marketing materials, as well as any synthetic cannabinoids.
- (8) **Water activity.** Testing for water activity is mandatory for solid and semi-solid edible cannabis products that do not require preservation by other means (e.g. refrigeration) and for cannabis plant material that is dried and prepared as a product in its final form of intended use and that is to be sold or transferred by a cultivation facility, products manufacturing facility or cannabis store.
- C.B.  A registered or licensed cultivation facility, registered or licensed products manufacturing facility, registered inherently hazardous extraction facility, registered or exempt caregiver, or registered dispensary may submit for research and development purposes samples of cannabis, but such testing shall not be considered mandatory, and cannabis that is transferred to a cannabis store licensee or consumer must then undergo mandatory testing.
- C.B.  A registered or licensed cultivation facility, registered or licensed products manufacturing facility, registered inherently hazardous extraction facility, registered or exempt caregiver, or registered dispensary may submit for research and development purposes samples of marijuanacannabis, but such testing shall not be considered mandatory, and marijuanacannabis that is transferred to a cannabis store licensee or consumer must then undergo mandatory testing.
- D.C.  OCP or its designee will publish a best practices guidance document that includes examples of a sampling plan and preservation instructions appropriate to each matrix type.
- E.D.  A cannabis testing facility must perform, and provide a certificate of analysis for, any test(s) requested by the CDC or OCP on any sample.

### Section 6.3 - Testing Methodology

- A. Testing facilities must develop and implement scientifically valid testing methodologies for the chemical, physical and microbial analysis of cannabis and cannabis products. A method validated in accordance with this section is deemed a scientifically valid testing methodology. The cannabis testing facility must not perform testing using a method that has not been validated.
- B. To the extent practicable, the cannabis testing facility's testing methodologies must comport with the following guidelines:
- (1) U.S. Food and Drug Administration's Bacterial Analytical Manual, most recent version of target method;
  - (2) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 21<sup>st</sup> Edition, 2019;
  - (3) Methods of analysis for contaminant testing published in the United States Pharmacopeia and the National Formulary (USP-NF) most recent version of target method; or
  - (4) If the cannabis testing facility wants to use an alternative scientifically valid testing methodology, the cannabis testing facility must validate the methodology and submit the validation study and standard operating procedure for the new methodology to the CDC.

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## Section 6.4 - Validation of Non-Standard Test Methods or Technologies and Modified Standard Test Methods or Technologies

- A. The [cannabis](#) testing facility may use a nonstandard method, including the use of a technology or instrumentation that is not one of the suggested instrumentations indicated in this rule, and including the use of a [cannabis](#) testing facility-designed or -developed method, a standard method used outside its intended scope or an amplification or a modified standard method for the analysis of samples, so long as the [cannabis](#) testing facility receives CDC certification for the use of such a nonstandard method.
- B. The [cannabis](#) testing facility must validate a desired method to use for the analysis of samples for each matrix. The [cannabis](#) testing facility must use one of the following guidelines, or equivalent methodologies, for validating a method, depending on the type of method:
  - (1) U.S. Food and Drug Administration's Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds, 3rd Edition, 2019; or
  - (2) U.S. Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 3rd Edition, 2019.
- C. At a minimum, the [cannabis](#) testing facility must conduct a level-one (emergency-use) single-[cannabis](#) testing facility validation study for all methods for testing for microbiological impurities or chemicals.
- D. A [cannabis](#) testing facility must include and address the criteria listed in Table 6.4-A in the [cannabis](#) testing facility's level-one validation study.

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**Table 6.4-A. Microbiological-analysis method validation studies**

Criteria	Requirement
Number of target organisms; inclusivity	5
Number of non-target organisms; exclusivity	5
Number of analyte levels per matrix: Qualitative methods	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: Quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level
Reference method comparison	No

- E. For purposes of validating standards for microbiological analysis, the following definitions apply:
- (1) “Exclusivity” is the specificity of the test method. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.
  - (2) “Inclusivity” is the sensitivity of the test method, meaning its capability to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.
- F. For chemical analysis method validation studies:
- (1) When high-concentration reference standards are available, testing facilities must employ direct spiking of the sample matrix.
  - (2) When high-concentration standards for matrix spiking are unavailable, matrix spikes may be made through post-processing and dilution spiking of samples before analysis, rather than direct sample-matrix spike.
- G. Testing facilities must use reference materials validation studies when [marijuanacannabis](#) reference materials become available.

## Section 6.5 - Certificate of Analysis

- A. For each primary sample of a batch tested, the [marijuanacannabis](#) testing facility must generate and provide a certificate of analysis to the requester and the CDC within two business days of the completion of the final data review.
- B. The certificate of analysis must, at a minimum, contain the following information:
- (1) [MarijuanaCannabis](#) testing facility’s name, mailing address and physical address;
  - (2) Sample-identifying information, including matrix type and unique sample identifiers;
  - (3) Sample history, including date collected, date received by the [marijuanacannabis](#) testing facility, whether the sample was collected by the [marijuanacannabis](#) testing facility or received from a licensee and date or dates of sample preparations and analyses;

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- (4) If applicable, the identity of the test methods used to analyze cannabinoids, residual solvents, pesticides, microbiological contaminants, mycotoxins, heavy metals and, if applicable, terpenes;
- (5) If applicable, test results for sample homogeneity; cannabinoids; residual solvents; pesticides; microbiological contamination; and, if applicable, terpenes;
- (5)(6) The laboratory uncertainty for potency analysis;
- (6)(7) If applicable, test results for water activity and visual inspection for filth and foreign material;
- (7)(8) The reporting limit for each analyte tested;
- (8)(9) The total primary sample weight in grams, reported to three significant figures;
- (9)(10) Whether the primary sample and batch “passed” or “failed” cannabis testing facility testing;
- The licensee for whom the testing was performed, including license number, name and source package identification number;
- (10)(11) and
- (11)(12) A disclaimer that not all potential/existing hazards were tested.
- C. The cannabis testing facility must validate the accuracy of the information contained in the certificate of analysis, and the facility director or QAO must sign and date the certificate of analysis.
- D. In the event that an error is discovered following the issuance of the certificate of analysis, the cannabis testing facility must correct the error through the correction and reissuance of the certificate of analysis to correct the error. The corrected certificate of analysis must state that is a reissued version of a previous certificate of analysis and must include the original sample identifiers as well as the reason for reissuance.
- D.E. A cannabis testing facility shall submit electronic data deliverables of all certificates of analysis in the electronic format designated by the CDC in accordance with 10 MRS §9418 (2)(A).

#### Section 6.6 - Cannabinoids

- A. When testing cannabinoid profile, the minimum representative sample size of 0.5 grams is required for all cannabis and cannabis products.
- B. When testing cannabinoid profile, the cannabis testing facility must minimally test for and report measurements for the following cannabinoids stated in Table 6.6-A:

**Table 6.6-A. Cannabinoid Potency**

Cannabinoid Potency as % of weight
Δ <sup>9</sup> -THC
THCA
CBD
CBDA
Total THC (as sum of THCA and delta-9 THC)
Total CBD (as sum of CBDA and CBD)

Note: Testing Facility calculation (only for instrumentation that does not employ heat for analysis) for Total THC = delta-9 THC + (THCA\*0.877) and Total CBD = CBD + (CBDA\*0.877). LC = Liquid Chromatography; DAD = Diode Array Detector; MS = Mass spectrometry; GC = Gas chromatography; FID = Flame ionization detector

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C. For samples of cannabis flower, non-edible cannabis products and cannabis concentrate, the cannabis testing facility must report, to three significant figures, the concentration in milligrams per gram (mg/g) of the cannabinoids listed in Table 6.6-A. For edible cannabis products, the cannabis testing facility must report, to three significant figures, the concentration in milligrams per serving (mg/serving) and milligrams per package (mg/package) of total THC in the product. The cannabis testing facility must report this information in the certificate of analysis.

D. When determining whether a sample of cannabis product exceeds the 10 mg/serving and 100 mg/package limits, the cannabis testing facility must account for an allowable variance of 10% in accordance with 28-B MRS § 703.

(1) When determining whether a serving of edible cannabis products exceeds the potency limits, the cannabis testing facility may account for the following variance in the potency in excess of 10 mg/serving:

- (a) Laboratory uncertainty, not to exceed 5% or 0.5 mg/serving;
- (b) An additional 10% allowable variance for edible cannabis products, which cannot exceed 1 mg/serving;
- (c) For a total maximum allowable potency of 11.5 mg of Total THC/serving;

(2) When determining whether a multi-serving package of edible cannabis products exceeds the potency limits, the cannabis testing facility may account for the following variance in the potency in excess of 100 mg/package:

- (a) Laboratory uncertainty, not to exceed 5% or 5 mg/package;
- (b) An additional allowable variance of up to 5 mg/package;
- (c) For a total maximum potency per multi-serving package of edible cannabis products of 110 of Total THC/package.

C.E. When determining whether a sample of cannabis product exceeds the 10 mg/serving and 100 mg/package limits required by 28-B MRS § 703, the cannabis testing facility must account for laboratory uncertainty, but under no circumstances may such uncertainty exceed 5%.

D.F. The cannabis testing facility may test for, and provide test results for, additional cannabinoids, if requested to do so by the client of the cannabis testing facility; however, these additional tests will not be certified by the CDC.

F.G. When testing for homogeneity of cannabinoids in cannabis products:

F.G. When testing for homogeneity of cannabinoids in marijuanacannabis products:

- (1) The cannabis testing facility must perform a homogeneity test for Total THC or Total CBD, whichever is purported by the manufacturer to be the largest ingredient content, for each production batch. If the amounts of Total THC and Total CBD are very similar (near 1:1), the cannabis testing facility must test for homogeneity of Total THC.
- (2) A homogeneity test requires at least two increments, collected separately from those collected for the field primary sample, from different regions of the production batch, and analyzed as separate samples. Sample collection must be in accordance with procedures in the OCP's best practices guidance document for sampling cannabis for mandatory testing purposes and the cannabis testing facility's standard operating procedure for sampling.
- (3) The cannabis testing facility must determine the relative standard deviation of Total THC or Total CBD content using test results of the two separately collected increments and the field primary sample collected for potency analysis. If the relative standard deviation is greater than 15%, then the batch "fails" the homogeneity test.

(4) OCPcannabis When testing for homogeneity of edible cannabis products, a minimum size sample

OCP

- (5) ~~If the product batch passes homogeneity testing, the marijuanacannabis testing facility may perform all other analyses required under this rule.~~

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When testing for homogeneity of edible cannabis products, a minimum size sample of 0.5 grams per increment is required.

- (1) The number of samples required for analysis is specified in Table 5.5-A. Each increment constitutes one packaged unit.
- (2) Total THC and, if applicable, Total CBD values between samples must not vary by more than 15% or the product fails testing.

G. If a batch fails homogeneity testing, the batch may be remediated and retested.

## Section 6.7 - Residual Solvents and Processing Chemicals

- A. The minimum sample size of 0.5 grams of representative sample is required for residual solvent analysis.
- A. The minimum sample size of 0.5 grams of representative sample is required for residual solvent analysis.
- B. The cannabis testing facility must analyze samples in each production batch for residual solvents and processing chemicals, including but not limited to inherently hazardous substances, in accordance with Table 6.7-A.
  - (1) A licensee is not required to test a cannabis product for residual solvents, poisons and toxins if all cannabis concentrate used to make the cannabis product has previously passed mandatory testing for residual solvents.
  - (1)(2) The cannabis testing facility is not required to analyze for residual solvents and processing chemicals in dried flower, kief and hashish or cannabis products manufactured without chemical solvents.
  - (2)(3) The cannabis testing facility is not required to analyze an orally-consumed tincture cannabis product containing alcohol for residual ethanol.
- C. For the purposes of residual solvent testing, the cannabis testing facility must report that the sample “passed” residual-solvent testing, if the concentrations of residual solvents are reported at or below the residual solvents and processing chemicals action levels in Table 6.7-A below.  
cannabis
- D. The cannabis testing facility must report the solvents and processing chemicals listed in this section, in parts per million (ppm) to three significant figures. The cannabis testing facility must report this information in the certificate of analysis.
- E. The cannabis testing facility must test both the concentrations of solvents and processing chemicals in the sample within the certificate of analysis, as well as document clearly whether the sample “passed” or “failed” residual solvent and processing-chemicals testing.
- F. If the sample fails residual solvent testing, the batch may be remediated in accordance with all applicable rules from OCP.
- G. A remediated batch that previously failed a test due to exceeding the action levels for residual solvents must be retested for solvents.
- ~~H. The batch must be destroyed when it is either not remediated, or a sample from the remediated batch fails testing.~~

**Table 6.7-A. Concentration Limits for Residual Solvents, (mg/kg)**

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Chemical Name	CAS No.	<u>Marijuana Cannabis Product (ppm)</u>
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Butanes <sup>a</sup>	106-97-8	5000
Ethanol <sup>b</sup>	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Heptanes	142-82-5	5000
Hexane <sup>**</sup>	110-54-3	290
Isopropyl alcohol <sup>b</sup>	67-63-0	5000
Methanol	67-56-1	3000
Pentane	109-66-0	5000
Propane <sup>a</sup>	74-98-6	5000
Toluene <sup>**</sup>	108-88-3	890
Total Xylenes (m, p, o-xylenes) <sup>**</sup>	1330-20-7	2170
1,2-Dichloroethane	107-06-2	1
Benzene <sup>**</sup>	71-43-2	1
Chloroform	67-66-3	1
Ethylene oxide	75-21-8	1
Methylene chloride	75-09-2	1
Trichloroethylene	79-01-6	1
Any other solvent detected not permitted for use		None Detected

<sup>\*\*</sup> Due to the possible presence in the solvents approved for use, limits have been listed accordingly

Note:

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- a) USP does not provide residual solvent limits for this solvent, the default USP Class 3 limits for acceptable use solvents was assigned as a limit.
- b) Products that are orally consumed and/or topically applied are exempt from ethanol limits.

## Section 6.8 - Residual Pesticides and Growth Regulators

- A. The minimum sample size is 0.5 grams of representative samples for all cannabis and cannabis products.
- B. The cannabis testing facility must test all cannabis samples for residual pesticides, including plant regulators, to ensure pesticide use and use of plant regulators are in compliance with applicable rules related to pesticides.
  - (1) A licensee is not required to test a cannabis concentrate or a cannabis product for pesticides, fungicides, insecticides and growth regulators if all cannabis flower and/or trim used to make the cannabis concentrate or cannabis product has previously passed mandatory testing for pesticides, fungicides, insecticides and growth regulators.
- B.C. The results of pesticide analyses must be less than
  - the limits identified in Table 6.8-A below.
  - the limits identified in Table 6.8-A below.
  - the limits identified in Table 6.8-A below.
  - the limits identified in Table 6.8-A below.
- C.D. The cannabis testing facility must report the levels detected in micrograms per kilogram (µg/kg) to three significant figures in the certificate of analysis. If a sample is found to contain pesticides above the cannabis limits listed in Table 6.8-A, the sample “fails” pesticide testing.
- D.E. The cannabis testing facility must analyze samples for the pesticides listed in Table 6.8-A below
  - utilizing analytic procedures in accordance with 7 CFR, Part 205 and the Official Methods of Analysis of
  - utilizing analytic procedures in accordance with 7 CFR, Part 205 and the Official Methods of Analysis of
  - utilizing analytic procedures in accordance with 7 CFR, Part 205 and the Official Methods of
  - Analysis of the AOAC International or other current applicable validated methodologies for determining the presence of contaminants in agricultural products.
- E.F. Batches of cannabis or cannabis products that fail testing for pesticides may not be remediated but may be retested in accordance with the requirements of 18-691 CMR, ch. 1.
  - (2) If result(s) of pesticide analysis indicates the presence of any of the prohibited pesticides, or, if, as an approved pesticide, test result is in excess of the tolerances or maximum residue limits (MRLs) determined unsafe or potentially harmful by the US Environmental Protection Agency (US EPA) for that pesticide, the batch fails.
- The list of pesticides and growth regulators in Table 6.8-A and Appendix A is not comprehensive, however, the vast majority of available pesticide products are prohibited from use on marijuanacannabis. Using a pesticide or growth regulator on a site for which it is not labeled or applying a pesticide or growth regulator in a manner inconsistent with label instructions is a violation of State and Federal law.
- E.F. Batches of marijuanacannabis or marijuanacannabis products that fail testing for pesticides may not be remediated but may be retested in accordance with the requirements of 18-691 CMR, ch. 1.

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**Table 6.8-A. Concentration Limits for Pesticides, Fungicides and Growth Regulators, (mg/kg)**

<u>Pesticide</u>	<u>MarijuanaCannabi s Product (ppm)</u>	<u>Pesticide</u>	<u>MarijuanaCannabi s Product (ppm)</u>
<u>Abamectin</u>	<u>0.5</u>	<u>Imazalil</u>	<u>0.2</u>
<u>Acephate</u>	<u>0.4</u>	<u>Imidacloprid</u>	<u>0.4</u>
<u>Acequinocyl</u>	<u>2</u>	<u>Kresoxim-methyl</u>	<u>0.4</u>
<u>Acetamiprid</u>	<u>0.2</u>	<u>Malathion</u>	<u>0.2</u>
<u>Aldicarb</u>	<u>0.4</u>	<u>Metalaxyl</u>	<u>0.2</u>
<u>Azoxystrobin</u>	<u>0.2</u>	<u>Methiocarb</u>	<u>0.2</u>
<u>Bifenazate</u>	<u>0.2</u>	<u>Methomyl</u>	<u>0.4</u>
<u>Bifenthrin</u>	<u>0.2</u>	<u>Methyl parathion</u>	<u>0.2</u>
<u>Boscalid</u>	<u>0.4</u>	<u>MGK-264</u>	<u>0.2</u>
<u>Carbaryl</u>	<u>0.2</u>	<u>Myclobutanil</u>	<u>0.2</u>
<u>Carbofuran</u>	<u>0.2</u>	<u>Naled</u>	<u>0.5</u>
<u>Chlorantraniliprole</u>	<u>0.2</u>	<u>Oxamyl</u>	<u>1</u>
<u>Chlorfenapyr</u>	<u>1</u>	<u>Paclobutrazol</u>	<u>0.4</u>
<u>Chlorpyrifos</u>	<u>0.2</u>	<u>Permethrins<sup>1</sup></u>	<u>0.2</u>
<u>Clofentezine</u>	<u>0.2</u>	<u>Phosmet</u>	<u>0.2</u>
<u>Cyfluthrin</u>	<u>1</u>	<u>Piperonylbutoxid e</u>	<u>2</u>
<u>Cypermethrin</u>	<u>1</u>	<u>Prallethrin</u>	<u>0.2</u>
<u>Daminozide</u>	<u>1</u>	<u>Propiconazole</u>	<u>0.4</u>
<u>Diazinon</u>	<u>0.2</u>	<u>Propoxur</u>	<u>0.2</u>
<u>DDVP (Dichlorvos)</u>	<u>1</u>	<u>Pyrethrins<sup>2</sup></u>	<u>1</u>
<u>Dimethoate</u>	<u>0.2</u>	<u>Pyridaben</u>	<u>0.2</u>
<u>Ethoprophos</u>	<u>0.2</u>	<u>Spinosad</u>	<u>0.2</u>
<u>Etofenprox</u>	<u>0.4</u>	<u>Spiromesifen</u>	<u>0.2</u>
<u>Etoxazole</u>	<u>0.2</u>	<u>Spirotetramat</u>	<u>0.2</u>

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<u>Fenoxycarb</u>	<u>0.2</u>	<u>Spiroxamine</u>	<u>0.4</u>
<u>Fenpyroximate</u>	<u>0.4</u>	<u>Tebuconazole</u>	<u>0.4</u>
<u>Fipronil</u>	<u>0.4</u>	<u>Thiacloprid</u>	<u>0.2</u>
<u>Flonicamid</u>	<u>1</u>	<u>Thiamethoxam</u>	<u>0.2</u>
<u>Fludioxonil</u>	<u>0.4</u>	<u>Trifloxystrobin</u>	<u>0.2</u>
<u>Hexythiazox</u>	<u>1</u>		

Note: 1. Permethrins are measured as cumulative residue of cis- and trans- permethrin isomers. (CAS numbers 54774-45-7 and 51877-74-8 respectively). 2. Pyrethrins are measured as cumulative residues of Pyrethrin, Cinerin, and Jasmolin (CAS number 8003-34-7).

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## Section 6.9 - Heavy Metals

- A. The minimum representative sample size is 0.5 grams of all marijuanacannabis and marijuanacannabis products.
- B. When testing for heavy metals, the marijuanacannabis testing facility must analyze all samples for concentrations of the heavy metals listed in Table 6.9-A below.
  - ~~B.(1)~~ A licensee is not required to test a cannabis product for other harmful chemicals (heavy metals) if the cannabis concentrate used to make the cannabis product has previously passed mandatory testing for the other harmful chemicals (heavy metals).
- C. The marijuanacannabis testing facility must report the concentration of each heavy metal in micrograms per kilogram (µg/kg) in the certificate of analysis.
- D. The marijuanacannabis testing facility must report that the sample "passed" heavy metal testing, if the concentrations of heavy metals listed in the table below are below the following heavy metal action levels.
- E. The marijuanacannabis testing facility may test for and report test results for additional metals, if the instrumentation detects additional metals in the samples, or if requested by the State or the client of the marijuanacannabis testing facility testing.
- F. Batches of marijuanacannabis or marijuanacannabis products that fail testing for pesticides metals may not be remediated but may be retested in accordance with the requirements of 18-691 CMR, ch. 1.

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Table 6.9-A. Concentration Limits for Metals, (µg/kg)

Heavy Metal	Inhalation (ppb)	Ingestion or Suppository (ppb)	Topical Application (ppb)
Cadmium (Cd)	200	500	5000
Lead (Pb)	500	500	10,000
Arsenic (As)	200	1500	1000
Mercury (Hg)	100	3000	1000

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AA—Atomic Adsorption; ICP—Inductively-Coupled Plasma; OES—Optical Emission Spectrometry;

MS—Mass Spectrometry; CVAA—Cold Vapor Atomic Absorption Review USP 2232

\*These limits apply to ~~marijuanacannabis~~ and ~~marijuanacannabis~~ concentrate intended for ingestion, inhalation or dermal application. These limits are based on inhalation limits described in USP<232> Elemental Impurities-Limits.

## Section 6.10 - Microbiological Impurities

- A. The minimum, representative sample size of 1.2 grams of finished plant material is required for analysis. The minimum representative sample size of 1.0 g of ~~edible-cannabis~~ products is required for analysis. The minimum representative sample size of 1.0 g of marijuanacannabis concentrate is required for analysis.
- B. ~~The marijuanacannabis testing facility must also test all marijuanacannabis concentrates for microbiological impurities.~~ For the purposes of microbiological testing, the ~~marijuanacannabis~~ testing facility must report that the sample “passed” microbiological-impurity testing if the contaminants listed in Table 6.10-A below do not exceed the limits. If the ~~marijuanacannabis~~ product is found to have a contaminant in levels exceeding those established as permissible under this rule, then it failed ~~contaminant microbial~~ testing.
- B.
- C. If a processing method can effectively sterilize the batch, then the batch may be:
- (1) ~~Used to make a concentrate or extract (if unprocessed); or~~
  - (2) ~~Further processed (if processed); or~~
  - (3) C. Destroyed. A licensee may attempt to remediate a batch of finished plant material or marijuanacannabis concentrate that fails microbial testing.
- D. If the licensee chooses ~~the option~~ to remediate following a failed fungus or mold test, the batch will need to be retested by the same ~~marijuanacannabis~~ testing facility and ~~will need to shall~~ include mycotoxin analysis. ~~This will include, including~~ Aflatoxins (B1, B2, G1 and G2) and Ochratoxin A. The total combined result of the five required mycotoxins must be less than 20 µg/kg to be considered a passing result.

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Table 6.10-A. Limits for Microbiological Contaminants in CFU/g

<del>MarijuanaCan</del> <u>nabis</u> Material	Total Viable Aerobic Bacteria	Total Yeast and Mold	Total Coliform Bacteria	Enterobacteriaceae	E. coli (STEC) and Salmonella (spp.)
<del>Unprocessed</del> <del>and Processed</del> Plant Material					

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and Cannabis Products	10 <sup>5</sup>	10 <sup>4</sup>	10 <sup>3</sup>	10 <sup>3</sup>	<1/g sample
CO <sub>2</sub> and Solvent-Based Extracts Concentrates or Cannabis Products	10 <sup>4</sup>	10 <sup>3</sup>	10 <sup>2</sup>	10 <sup>2</sup>	<1/g sample

Based on analytical limits based on American Herbal Pharmacopoeia, Revision 2014.

E. The ~~marijuanacannabis~~ testing facility must report the concentration of each mycotoxin in micrograms per kilogram (µg/kg) to three significant figures in the certificate of analysis.

E.F. ~~The marijuanacannabis testing facility must report the concentration of all other microbials total aerobic bacteria, total yeast and mold, total Coliform bacteria and Enterobacteriaceae in CFU/g to two significant figures in the certificate of analysis.~~

E.G. The ~~marijuanacannabis~~ testing facility must report whether the strains listed in Table 6.10-A are detected, or are not detected, in 1.0 gram. The ~~marijuanacannabis~~ testing facility must report this information in the certificate of analysis. If any strains are detected above limits set in Table 6.10-A above, the batch fails testing and may not be released for sale.

E.H. ~~The marijuanacannabis~~ testing facility may test for and provide test results for additional microorganisms if requested.

## Section 6.11 - Water Activity ~~and Moisture Content~~

- The minimum representative sample size of 0.5 grams of dried flower and 1.0 g of edible products is required for analysis.
- If the water activity in a dried flower production batch sample is at or below, 0.65 A<sub>w</sub>, the sample “passes” water-activity testing.
- If the water activity in solid and semi-solid edible ~~marijuanacannabis~~ products that do not require additional preservation (e.g. refrigeration) is at, or below, 0.85 A<sub>w</sub>, the sample “passes” water-activity testing.
- ~~The marijuanacannabis testing facility must report the moisture content of dried flower, trim and other plant material that has been dried, cured or otherwise prepared in a manner to reduce or eliminate moisture from the plant material.~~
- ~~The marijuanacannabis testing facility must report the water-activity level of the sample in A<sub>w</sub> and the moisture content of the sample in percent to two significant figures.~~
- ~~Batches of marijuanacannabis or marijuanacannabis products that fail testing for water activity may be remediated and/or retested in accordance with the requirements of 18-691 CMR, ch. 1.~~
- The ~~marijuanacannabis~~ testing facility must report this information in the certificate of analysis.
- The ~~marijuanacannabis~~ testing facility may provide additional information on ~~moisture content and~~ water activity results, if the ~~marijuanacannabis~~ testing facility determines that it is important, or if it is requested.

## Section 6.12 - Visual Inspection for Filth and Foreign Material

- The minimum sample size is 0.5 grams of representative samples.

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- B. The cannabis testing facility must visually inspect all samples for signs of filth and foreign material present in the sample. “Filth and foreign material” includes, but is not limited to, hair, insects, feces, packaging contaminants and manufacturing waste and by-products.
  - (1) The samples shall not pass if any living or dead insect, at any life cycle stage; one hair; or one count of mammalian excreta is found.
  - (2) The sample shall not pass if more than one fourth of the total area is covered by mold, sand, soil, cinders, dirt or imbedded foreign material.
- C. The cannabis testing facility must report in the certificate of analysis whether the sample “passed” or “failed” visual inspection for filth and foreign material.
  - (1) If it fails visual inspection for filth and foreign material, the batch fails testing.
  - (2) A production batch that fails must be destroyed unless it can be remediated pursuant to any rules of OCP.
  - (3) Failed batches not successfully remediated must be destroyed.

### Section 6.13 - Terpenes

- A. The cannabis testing facility may also report individual terpene results, as requested.
- B. If the product labeling reports that the sample contains discrete terpenes, the cannabis testing facility must test for those terpenes. The cannabis testing facility must report to one-hundredth of a percent the concentration in percentage in the certificate of analysis.

### Section 6.14 - Quality Control

- A. The cannabis testing facility must use quality control samples in the performance of each assay for chemical and microbiological analyses.
  - (1) The cannabis testing facility must analyze the quality control samples in the exact same manner as the test samples, to validate the testing results.
- B. The cannabis testing facility must run quality control samples with every analytical batch of samples. For chemical analyses, the cannabis testing facility must prepare and analyze samples in batches of up to 20 samples, to include a method blank, a laboratory control sample, a sample duplicate, a matrix spike sample, and a certified reference material when available.
  - (1) A method blank means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation.
    - (a) Method blanks are analyzed under the same conditions, including sample preparation steps, as the other samples in the analytical batch to demonstrate the analytical process does not introduce contamination.
    - (b) If the method blank contains analyte(s) of interest greater than half of the reporting limit or limit of quantitation, but below the limit of quantitation, the data must be flagged with a “B” and an explanation noted in the certificate of analysis.
    - (c) If the method blank contains analyte(s) of interest above the limit of quantitation, it may be reanalyzed once. If the method blank is still above the limit of quantitation, the cannabis testing facility must seek to locate and reduce the source of the contamination, and then the entire batch must be re-prepared and reanalyzed. If the method blank results still do not meet the acceptance criteria, and/or reanalysis is not practical, then the cannabis testing facility must halt performing the analysis until resolution of this issue. Resolution of the issue requires the reduction of method blank measurements below the limit of quantification.

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- (c)(d) In instances where the method blank contains analyte(s) of interest above the limit of quantitation but the samples in the associated batch do not contain any level of those specific analytes, the data for that batch may be reported as flagged as described in (b) above. If any of the samples in the batch contain those analytes at levels above the limit of quantitation, then that data cannot be reported, and the issue must be resolved before running further samples.
- (2) A laboratory control sample means a simplified sample matrix, free from analytes of interest, spiked with known amounts of analytes, using a second source standard (a standard obtained from a different supplier than the calibration standards), where available, and taken through all sample preparation and analytical steps of the procedure, unless otherwise noted in a reference method (also known as a laboratory fortified blank, spiked blank or quality control check sample).
- (a) When reference standards are commercially available in usable concentrations, and are applicable to the method being run, the cannabis testing facility must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples.
- (a)(b) The cannabis testing facility must calculate the percent recovery for quantitative chemical analysis, for the laboratory control sample spiked with a known amount of reference standard. The acceptable percent recovery is  $\pm 20\%$ .
- (b)(c) If the percent recovery is outside of the acceptable range, the cannabis testing facility must investigate the cause, correct the problem and re-run the batch of samples, if possible. If the problem persists, the cannabis testing facility must re-prepare the batch of samples and run the analysis again, if possible. If a laboratory control sample is performed and fails, it must be flagged with “\*” and an explanation noted in the certificate of analysis.
- (3) A sample duplicate means a separate aliquot of the sample carried through the complete preparation and analytical procedure.
- (a) The acceptance criteria between the primary sample and the duplicate sample must be less than 20% relative percent difference. Relative percent difference is calculated using the following equation:  $RPD = \frac{|(\text{primary sample measurement} - \text{duplicate sample measurement})|}{[(\text{primary sample measurement} + \text{duplicate sample measurement}) / 2]} \times 100\%$ .
- (b) Limits must be set at <20% until enough data points are established to create lab defined limits. At no point can lab calculated limits be greater than the 20% listed in this rule.
- (c) If the RPD exceeds the acceptance limits for a sample duplicate, it must be flagged with a “\*” and an explanation noted in the certificate of analysis.
- (4) A matrix spike means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.
- (a) When reference standards are commercially available in usable concentrations and are applicable to the method being run, the cannabis testing facility must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples. The matrix spike sample must be prepared with all of the target analytes for that analysis with the exception of (b) below.
- (a)(b) For potency analysis, if a commercial reference standard is not available in usable concentrations, a cannabis testing facility may develop an in-house reference material as a spiking standard to be used in that analysis as described in Section 6.13 B (5) (b) below. This spiking standard must contain at least one of the required target analytes for potency analysis.

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- (b)(c) The cannabis testing facility must calculate the percent recovery for quantitative chemical analysis by analyzing an aliquot of sample spiked with a known amount of reference standard. An aliquot of the sample is analyzed without the spike, and the result is subtracted from the spiked value. The sample result, after subtraction, is divided by the expected result and multiplied by 100. If interferences are present in the sample, results may be significantly higher or lower than the actual concentration contained in the sample. The acceptable percent recovery is 70% to 130%.
- (d) If the percent recovery is outside of the range, the cannabis testing facility must investigate the cause, correct the problem and re-run the batch of samples, if possible. If the problem persists, the cannabis testing facility must re-prepare the samples and run the analysis again, if possible. If a matrix spike is performed and fails, it must be flagged with an “\*” and an explanation noted in the certificate of analysis.
- (5) A certified reference material (CRM) means a reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute. The CRM must be in a matrix comparable to the samples being analyzed.
- (a) When commercially available at a reasonable cost, a certified reference material must be obtained from an outside source.
- (b) If an in-matrix CRM is not available from an outside source, the cannabis testing facility may make its own in-house reference material. In-house reference material must contain verified amounts of analytes determined by analyzing a batch of thoroughly homogenized sample material a minimum of ten times and using the average result of those ten replicate analyses as the accepted verified value.
- (c) The CRM must fall within the quality control acceptance criteria given in its certificate, criteria given in a referenced test method, or be within +/- 20% of the given value, whichever is most stringent. If an in-house reference material is used, the result must fall within +/-20% of the verified value as determined in (b) above. If the result does not meet these criteria, the cannabis testing facility must investigate the cause, correct the problem and re-run the batch of samples, if possible. If the problem persists, the cannabis testing facility must re-prepare the samples and run the analysis again, if possible. If a CRM or in-house reference material is performed and fails, it must be flagged with an “\*” and an explanation must be noted in the certificate of analysis.
- C. For microbiological analysis, the cannabis testing facility must prepare and analyze a negative control sample and a positive control sample for each new lot of testing media or reagent.
- (1) A negative control sample means a QC sample for microbiological testing that is expected to produce a reaction which indicates the absence of the target organism.
- (2) A positive control sample means a QC sample for microbiological testing that is expected to produce a reaction which indicates the presence of the target organism.
- (3) Positive and negative control samples are analyzed under the same conditions as samples in an analytical batch to demonstrate the analytical process does not adversely affect test results.
- (4) If the positive or negative control sample results do not meet acceptance criteria, the cannabis testing facility must investigate the cause, correct the problem, and rerun the positive and negative control samples. If the problem persists, the cannabis testing facility must reject the lot of testing media or reagent and use a new lot that passes QC testing.
- D. The cannabis testing facility must prepare calibration standards by diluting a standard solution to produce working standards used for calibration of the instrument and quantitation of analyses in samples.
- E. Cannabis testing facility must perform initial calibration of instruments and calibration verification.
- (1) Initial Calibration
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- a. Sufficient records must be retained to permit reconstruction of the instrument calibration such as calibration date, approved method identification, instrument, analysis date, each analyte name, the manual or electronic identification of the analyst performing the test, concentration and response, calibration curve or response factor or unique equation or coefficient used to reduce instrument responses to concentration.
  - b. Sample results must be quantitated from the most recent instrument calibration and may not be quantitated from any earlier instrument calibration verification.
  - c. All instrument calibrations must be verified with a standard obtained from a second source such as a different manufacturer, when available. Traceability must be to a national standard, when available.
  - d. Criteria for the acceptance of an instrument calibration shall include, at a minimum, a correlation coefficient not less than 0.99. Additional criteria used must be appropriate to the calibration technique employed and must be documented in the laboratory's SOP.
  - e. The following must occur for methods employing standardization with a zero point and a single point calibration standard:
    - (i) Before the analysis of samples, the linear range of the instrument must be established by analyzing a series of standards, one of which must encompass the single point quantitation level;
    - (ii) A zero point and a single point calibration standard must be analyzed with each analytical batch;
    - (iii) A standard corresponding to the RL must be analyzed with each analytical batch and must meet established acceptance criteria;
    - (iv) The linearity must be verified at a frequency established by the method or the manufacturer; and
    - (v) If allowed in the rule, a sample result within an analytical batch, higher than its associated single point standard, can be reported if the following conditions are met:
      - (1) A standard with a concentration at or above the analyte concentration in a sample must be analyzed and must meet established acceptance criteria for validating the linearity;
      - (2) The sample must be diluted such that the result falls below the single point calibration concentration; or
      - (3) The data must be reported with an appropriate data qualifier or an explanation in the narrative of the test report.
  - f. If the instrument calibration results are outside established acceptance criteria, corrective actions must be performed, and all associated samples reanalyzed. If reanalysis of the samples is not possible, data associated with an unacceptable instrument calibration must be appropriately qualified on the test report.
  - g. Calibration standards must include concentrations at or below the limit specified in the rule.
  - h. The minimum number of calibration standards shall be five, one of which must be at the RL, not including blanks or a zero standard, with the exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations. The cannabis testing facility must have an SOP that documents the protocol for determining the number of points required for the instrument calibration employed and the acceptance criteria for calibration.
  - i. It is prohibited to remove data points from within a calibration range while still retaining the extreme ends of the calibration range.
- (2) Calibration verification
- a. When an instrument calibration is not performed on the day of analysis, the instrument calibration must be verified before analysis of samples by analyzing a calibration standard with each batch.
  - b. Calibration verification must be repeated at the beginning of each batch, after every tenth sample, excluding QC samples, and at the end of each batch.

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- c. Sufficient raw data records must be retained to permit reconstruction of the calibration verification, such as: instrument; analysis date; each analyte name, concentration and response; calibration curve or response factor; or unique equations or coefficients used to convert instrument responses into concentrations. Calibration verification records must explicitly connect the verification data to the instrument calibration.
  - d. Criteria for the acceptance of calibration verifications must be established and evaluated using the same technique used to evaluate the instrument calibration.
  - e. If the calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then the cannabis testing facility must either demonstrate performance after corrective action by performing one successful calibration verification or perform a new instrument calibration. If the cannabis testing facility has not demonstrated acceptable performance after the corrective action, sample analyses must not occur until a new instrument calibration is established and verified. Sample data associated with unacceptable calibration verification may be reported as qualified data under the following special conditions if allowed in rule:
    - (i) When the acceptance criteria for the calibration verification are exceeded high (high bias) and all associated samples contain analytes below the RL, those sample results may be reported.
    - (ii) When the acceptance criteria for the calibration verification are exceeded low (low bias), the sample results may be reported if the concentration exceeds a maximum regulatory limit as defined by the rule.
  - f. When allowed by rule, verification procedures may result in a set of correction factors. If correction factors are employed, the cannabis testing facility must have procedures to ensure that copies of all data records, such as in computer software, are correctly updated.
  - g. Test equipment, including both hardware and software, must be safeguarded from adjustments that would invalidate the test results.
- F. The cannabis testing facility must store stock standards and reagents per manufacturer's recommendations and use or discard by manufacturer's expiration dates. All prepared standards and reagents must be traceable to stocks, and the date of preparations and expiration date must be traceable in facility documentation.
- G. If the response for a target analyte exceeds the working range of the calibration curve, the sample extract must be diluted and reanalyzed.
- F.H. For chemical analyses, a cannabis testing facility shall utilize an internal standard when possible, and for pesticide analyses, also use surrogate standards as appropriate.
- I. All quality control measures must be assessed and evaluated on an ongoing basis. QC acceptance criteria in the cannabis testing facility's QA manual must be used to determine the validity of data.
- G.J. All instrument method detection and reporting limit studies shall be completed at least annually, and upon a change in methodology.
- H.K. If the cannabis testing facility finds evidence that a sample is contaminated due to contamination in the sample collection process, the cannabis testing facility will contact the individual or entity responsible for sample collection to validate the sample collector or self-sampling licensee's decontamination procedure.
- I.L. Upon request by the CDC, the cannabis testing facility must in a timely manner generate and submit to CDC a quality control sample report that includes QC parameters and measurements, analysis date and matrix.
- J.M. CDC may require in writing reasonable additional quality control measures for any testing methodology as found in previously established Federal or State guidelines such as:
- (1) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 21<sup>st</sup> Edition, 2019;
  - (2) U.S. Food and Drug Administration's NCIMS 2400 Forms, Rev. 04/2019; or

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(3) State of Maine Comprehensive and Limited Environmental Laboratory Accreditation Rule, 10-144 CMR Ch. 263 (2018).

(3)N. CDC and OCP may require a cannabis testing facility to submit to interlaboratory testing at its discretion.

## Section 7 – Recordkeeping Requirements

### Section 7.1 - Recordkeeping Requirements

- A. The cannabis testing facility must maintain analytical records to demonstrate to the CDC the following: the analyst's name; date of analysis; approver of the certificate of analysis and relevant data package; the test method; and the materials used.
- (1) Cannabis testing facility recordkeeping may be on paper or on electronic, magnetic or optical media and must be stored in such a way that the data are readily retrieved when requested by the OCP or the CDC.
  - (2) If the cannabis testing facility recordkeeping is not on paper, the cannabis testing facility must be able to produce them in hard copy for OCP or the CDC, upon request.
  - (3) All cannabis testing facility records must be kept for a minimum of five years.
  - (4) OCP and the CDC must be allowed access to all electronic data, including standards records, calibration records, extraction logs, cannabis testing facility notebooks and all other cannabis testing facility-related documents listed below.
- B. The cannabis testing facility must maintain all documents, forms, records and standard operating procedures associated with the cannabis testing facility's methods, including without limitation the following:
- (1) Current personnel qualification, training and competency documentation, including, but not limited to, resumes, training records, continuing education records, analytical proficiency testing records and demonstration of capability records or attestations for cannabis testing facility work;
  - (2) Method verification and validation records, including records relating to method modification; method detection limit and reporting limit determination; ongoing verification, such as proficiency testing; and reference material analysis;
  - (3) Quality control and quality assurance records, including the cannabis testing facility's quality assurance manual and control charts with control limits;
  - (4) Any sample collection records the testing facility requires licensees to submit with every sample collected and submitted for mandatory testing, if applicable in accordance with the testing facility's quality system;
  - (5) Chain of custody records, including chain of custody forms, applicable field sample logs, and record relating to sample receipt, sample descriptions, sample rejections, laboratory information management system (LIMS), sample storage, sample retention and disposal;
  - (6) Records relating to purchasing and supply, purchase requisitions, packing slips, and supplier records;
  - (7) Certificates of analysis;
  - (8) Records of equipment installation, maintenance and calibration, including date; name of person performing the installation, calibration or maintenance; and description of the work performed; internal maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records and daily verification-of-calibration records;
  - (9) Customer service records, including include contracts with customers, customer request records, transaction records and customer feedback;

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- (10) Records related to the handling of complaints, nonconformities, and corrective action, including records of internal investigations, customer notifications and implementation of corrective action plans;
  - (11) Internal and external audit records, including audit checklists, standard operating procedures and audit observation and findings reports, including the date and name of the person or persons performing the audit;
  - (12) Management review records, including technical data review reports and final management review reports, with review date and the identity of the reviewer;
  - (13) Cannabis testing facility data reports, data review and data approval records, which must include the analysis date and the name of the analysts, including instrument and equipment identification records, records with unique sample identifiers, analysts' cannabis testing facility notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data and test-method raw data;
  - (14) Proficiency testing records, including the proficiency test schedule, proficiency test reports, and records of data review, data reporting, nonconforming work, corrective action, quality control and quality assurance;
  - (15) Electronic data, backed-up data, records regarding the protection of data and cannabis testing facility security records, including raw unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, authorized personnel records and cannabis testing facility access records and surveillance- and security-equipment records;
  - (16) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' cannabis testing facility notebooks and logbooks, supplier records and all other data-related records; and
  - (17) Cannabis testing facility contamination and cleaning records, including autoclave records, acid wash logs and records and general cannabis testing facility safety and chemical-hygiene protocols.
- C. If the records are missing or incomplete, or if the cannabis testing facility does not produce the records for OCP or the CDC upon request, OCP or the CDC may take disciplinary action against the cannabis testing facility. The cannabis testing facility shall have 7 calendar days from issuance of request to respond.

## Section 7.2 - Data Package Requests

- A. The cannabis testing facility must retain the entire data package for each sample the cannabis testing facility analyzes for a minimum of five years and make available to OCP or the CDC upon request. The data package must contain, at a minimum, the following information:
- (1) The name and address of the cannabis testing facility that performed the analytical procedures;
  - (2) Any sample collection records required by the testing facility's quality system, if applicable, for each batch of cannabis, cannabis concentrate or cannabis product submitted for mandatory testing;
  - (3) The names, functions and signatures of the cannabis testing facility personnel that performed sample preparation and analyses and reviewed and approved the data;
  - (4) All sample and batch quality control sample results;
  - (5) Raw data for each sample;
  - (6) Instrument raw data, if any;
  - (7) Instrument test method with parameters;
  - (8) Instrument tune report;
  - (9) All instrument calibration data;

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- (10) Test method worksheets or forms used for sample identification, characterization and calculations, including chromatograms, sample preparation worksheets and final datasheets;
  - (11) Quality control report with worksheets, forms or copies of cannabis testing facility notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials and standards used for analysis;
  - (12) Analytical batch sample sequences;
  - (13) The field sample log and the chain of custody form; and
  - (14) The certificate of analysis created, as required under this rule.
- B. The cannabis testing facility must make the data package for a sample available.
- C. After the data package has been compiled, the facility director or QAO must:
- (1) Review the analytical results for technical correctness and completeness;
  - (2) Verify that the results of each analysis carried out by the cannabis testing facility are reported accurately, clearly, unambiguously and objectively and that the measurements are traceable; and
  - (3) Approve the measurement results by signing and dating the data package prior to release of the data by the cannabis testing facility.
- D. The testing facility must submit requested sample results to the CDC in an electronic format acceptable to the Maine Cannabis Certification Program (MMCP). This includes the reporting of all required laboratory quality control information and associated acceptance limits.

### Section 7.3 - Electronic Data

- A. Testing facilities must store all raw unprocessed instrument output data files and processed quantitation output files on some form of electronic, magnetic or optical media. The cannabis testing facility must allow access to these records for inspection and audit.
- B. Testing facilities must install, manage and maintain password-protection for electronically stored data, including any certificate of analysis.

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## Section 8 – Waste Disposal Plan

### Section 8.1 – Waste Disposal SOP required

In addition to the SOPs required in Section 3 of this rule, a [cannabis](#) testing facility must possess and follow written SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products. All waste must be managed according to the following requirements:

- A. Solid waste, as defined in the *Maine Hazardous Waste, Septage and Solid Waste Management Act*, 38 MRS § 1303-C(29), must be managed in accordance with the *Solid Waste Management Rules*, 06-096 CMR, Ch. 400-425.
- B. The [cannabis](#) testing facility must destroy nonhazardous used or unused [cannabis](#) test samples in accordance with the facility's standard operating procedure and this rule.
- C. To render [cannabis](#) goods into [cannabis](#) waste, the [cannabis](#) testing facility must add the [cannabis](#) to other material not suitable for human consumption (e.g. agricultural manure suitable for composting, other compostable material) and mix it thoroughly. The resulting mixture must be at least 50% non-[cannabis](#) material. Licensees must render goods into [cannabis](#) waste one batch at a time and track that batch through its disposal in the statewide inventory tracking system.
- D. It is unlawful for any [cannabis](#) testing facility to dispose of [cannabis](#) goods or waste in a trashcan, dumpster or other similar receptacle, unless the nonhazardous goods or waste is composted and made unusable as described in this section. Testing facilities are required to quarantine [cannabis](#) goods on the premises for at least 3 business days to permit [OCP](#) time to investigate or witness the destruction process.
- E. The [cannabis](#) testing facility must document the quarantine, rendering into [cannabis](#) waste, and disposal or deposition of the [cannabis](#) waste. A [cannabis](#) testing facility may retain and utilize [cannabis](#) and [cannabis](#) products for use as standards or for method development.
- F. Hazardous wastes, as defined by 38 MRS § 1303-C(15), with the exception of infectious and pathogenic wastes, and in 06-096 CMR, Ch. 850, must be managed in accordance with Maine's Standards for Hazardous Waste Facilities Rules, Interim Licenses for Waste Facilities for Hazardous Wastes Rules, Licensing of Hazardous Waste Facilities Rules and Hazardous Waste Manifest Requirements (See 06-096 CMR, Chs. 850-857).
- G. If there is a conflict between another applicable rule or regulation and this rule, the more restrictive requirement applies.

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## Section 9 – Changes to Cannabis Testing Facility Operations

### Section 9.1 - Post-Certification Change Notification

- A. The cannabis testing facility must provide OCP and the CDC with a written notice of any change described below at least thirty calendar days prior to the proposed effective date of the change:
  - (1) Change in ownership of the cannabis testing facility as defined in Section 2 of this rule;
  - (2) Change in the cannabis testing facility's facility director or QAO;
  - (3) Changes in the approved location for an analysis;
  - (4) Major changes in analytical equipment;
  - (5) Change to approved premises floor plan submitted to OCP in the cannabis testing facility's license application, including without limitation proposed premises expansion;
  - (6) Discontinuation of, or failure to launch, cannabis testing facility activities.
- B. When there is a change in location or change in technology of analysis, the cannabis testing facility must provide results of proficiency testing samples or a demonstration of capability, analyzed in the new cannabis testing facility location or analyzed under a change in instrumentation.
- C. Unless the cannabis testing facility provides timely notification of the above changes and receives prior approval or waiver of the requirement of prior notice and approval by OCP and the CDC, the certification of the field of testing is void and must be returned to the CDC.
- C. Unless the ~~marijuana~~cannabis testing facility provides timely notification of the above changes and receives prior approval or waiver of the requirement of prior notice and approval by ~~OMPOCP~~OCP and the CDC, the certification of the field of testing is void and must be returned to the CDC.

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## Section 10 – Denial, Suspension, Limitation or Revocation of Certification by the CDC

### Section 10.1 - Denial, Suspension or Revocation of Provisional Certification

- A. The CDC may suspend a provisional certification if the provisional licensee fails to obtain ISO/IEC 17025:2017 or most recent version accreditation within the period of the original provisional certification.
- B. The CDC shall revoke a provisional certification if the provisional licensee is denied ISO/IEC 17025:2017 or most recent version accreditation.

### Section 10.2 - Denial, Suspension or Revocation of Certification

- A. The CDC may deny, revoke, suspend, or not renew the certification of any [cannabis](#) testing facility for engaging in conduct that includes, but is not limited to, the following:
  - (1) Failure to observe any term of certification;
  - (2) Failure to observe any order, request or other directive made under the statutory authority vested in [OCP](#) or the CDC;
  - (3) Engaging in, aiding, abetting, causing or permitting any action prohibited under 22 MRS, chapter 558-C or 28-B MRS, chapter 1;
  - (4) Failure to comply with any regulatory requirement of these rules and any other applicable state regulation or statute;
  - (5) Making false or deceptive representation on any application for certification or renewal thereof;
  - (6) Failure to maintain professional, competent and ethical standards of practice;
  - (7) Making false or deceptive representation of any testing results and reports thereof;
  - (8) Failure to provide timely and accurate data reporting;
  - (9) Engaging in false or deceptive advertising; or
  - (10) Providing services associated with product labeling for a licensed establishment, registered dispensary, or an exempt or registered caregiver; a principal officer, board member of a registered dispensary; or an employee or assistant of a registered dispensary or an exempt or registered caregiver who has a financial or other interest in the [cannabis](#) testing facility.
- B. The CDC may deny, revoke or suspend the certification of any [cannabis](#) testing facility if the municipality wherein the [cannabis](#) testing facility is located has informed [OCP](#) that it has revoked, suspended or not renewed local authorization of the [cannabis](#) testing facility.
- C. The CDC shall communicate any denial, suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.

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## Section 11 – Certification Fees for Testing Facilities

### Section 11.1 - CDC Certification Fees

The following fees are required for [cannabis](#) testing facility certification. However, these fees are subject to an annual maximum of \$2,500 per [cannabis](#) testing facility.

- A. Provisional Certification: A [cannabis](#) testing facility that has applied for but has not yet obtained ISO/IEC 17025:2017 or most recent version accreditation is required to pay a base fee of \$1,250 plus appropriate technology fees to apply for a provisional certification.
- B. Full Certification: The CDC shall issue full certification to a [cannabis](#) testing facility holding provisional certification in good standing once the [cannabis](#) testing facility provides proof of ISO/IEC 17025:2017 or most recent version accreditation and pays an application fee of \$500.
- C. Full Certification without Provisional Certification: An applicant that has received ISO/IEC 17025:2017 or most recent version accreditation but does not have provisional certification may apply for full certification directly. The [cannabis](#) testing facility is required to pay an application fee of \$1,000 for initial certification, plus applicable technology fees.
- D. Renewal: The [cannabis](#) testing facility is required to pay an annual application fee of \$1,000 plus appropriate technology fees to apply for annual recertification.
- E. Technology fees: An applicant must pay the fees listed in Table 11.1-A for each technology certified.

**Table 11.1-A. Technology Fees**

Analyte Category	Technology Fee
Microbiological Contaminants Visual Inspection Water Activity <a href="#">Moisture Content</a>	\$50 per technology
Metals	\$125 per technology
Solvents Pesticides Cannabinoids	\$150 per technology

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Section 11.2 - Payment of Certification Fees Required Prior to Full Active or Provisional Active  
Licensure

Section 11.2 - Payment of Certification Fees Required Prior to Full Active or Provisional Active  
Licensure

- A. OCP may not issue a provisional active license or active license until the applicant meets all requirements and pays all applicable fees.
- B. All applications or requests to change the scope of activities to be conducted under a cannabis testing facility license must be accompanied by the applicable fees specified in this section.
- C. Application fees apply to the addition of technologies for reinstatement after revocation or denial of licenses.
- D. Payment of fees must be in the form of a check or money order, made payable to the “Treasurer, State of Maine.”

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